US3722066 (Prod: Keystone VitaLink Research - Greenville - PPDS)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:11:02

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US3722066
Form: Participant Creation
Generated On: 26 Nov 2020 11:11:02

Participant ID	US3722066

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-6153831

US3722066
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	03 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-6153832

US3722066
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:11:02

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	67
Age Units	YEARS
Age (Derived)	68
Sex	Female ☐ Male ■
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ■ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

FDA-CBER-2022-1614-6153833

US3722066
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:11:02

Date of Informed Consent *(dd MMM yyyy)*	3 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ■ Amendment 2 ☐ Amendment 3 ☐ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ■ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ■
If Yes, previous participant number	
Enrollment Trigger	1

FDA-CBER-2022-1614-6153834

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

FDA-CBER-2022-1614-6153835

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-6153836

US3722066
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:11:02

Condition	HYPERTENSION
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)	

FDA-CBER-2022-1614-6153837

US3722066
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:11:02

Condition	HYPERCHOLESTEROL
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-6153838

US3722066
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:11:02

Condition	RESTLESS LEG SYNDROME
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-6153839

US3722066
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:11:02

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-6153840

US3722066
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:11:02

Condition	GERD
Start date (dd MMM yyyy)	UN JUL 1990
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)	JUL 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-6153841

US3722066
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 11:11:02

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1956
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 1956
Start Year (derived)	1956
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-6153842

US3722066
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 11:11:02

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1956
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 1956
Start Year (derived)	1956
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-6153843

US3722066
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 11:11:02

Condition	OSTEOARTHRITIS IN RIGHT KNEE AND HIP, BILATERAL THUMBS AND SHOULDERS
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-6153844

US3722066
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 11:11:02

Condition	TORE ROTATOR CUFF LEFT SHOULDER
Start date (dd MMM yyyy)	UN UNK 1972
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1972
Start Year (derived)	1972
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

FDA-CBER-2022-1614-6153845

US3722066
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 11:11:02

Condition	TORE ROTATOR CUFF RIGHT SHOULDER
Start date (dd MMM yyyy)	UN UNK 1972
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1972
Start Year (derived)	1972
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

FDA-CBER-2022-1614-6153846

US3722066
Folder: Screening
Form: Medical History (12)
Generated On: 26 Nov 2020 11:11:02

Condition	ABDOMINAL HERNIA
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

FDA-CBER-2022-1614-6153847

US3722066
Folder: Screening
Form: Medical History (13)
Generated On: 26 Nov 2020 11:11:02

Condition	VASECTOMY
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Start Year (derived)	1988
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-6153848

US3722066
Folder: Screening
Form: Medical History (14)
Generated On: 26 Nov 2020 11:11:02

Condition	IRON DEFICIENCY ANEMIA
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-6153849

US3722066
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	3 AUG 2020
Time of assessment *(00:00-23:59)*	17:11 (24 HR)
Vital Signs Date and Time (derived)	3 AUG 2020 17:11
Height *(xxx.x)*	167 cm
Weight *(xxx.x)*	88.9 kg
BMI *(xxx.x)*	31.87637 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-6153850

US3722066
Folder: Screening
Form: Physical Examination
Generated On: 26 Nov 2020 11:11:02

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	3 AUG 2020

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

FDA-CBER-2022-1614-6153851

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

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

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

FDA-CBER-2022-1614-6153853

US3722066
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	3 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-6153854

US3722066
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 11:11:02

What was the date of randomization? *(dd MMM yyyy)*	03 AUG 2020
What was the participant's randomization number?	184495
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 ■

FDA-CBER-2022-1614-6153855

Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-6153856

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02

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)*	3 AUG 2020
Time of assessment *(00:00-23:59)*	17:09 (24 HR)
Vital Signs Date and Time (derived)	3 AUG 2020 17:09
Temperature *(xxx.x)*	98.6 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	77 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	81 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-6153857

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02

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)*	3 AUG 2020
Time of assessment *(00:00-23:59)*	18:14 (24 HR)
Vital Signs Date and Time (derived)	3 AUG 2020 18:14
Temperature *(xxx.x)*	97.9 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	72 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	81 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-6153858

US3722066
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 26 Nov 2020 11:11:02

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-2022-1614-6153859

US3722066
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:11:02

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)*	3 AUG 2020
What was the treatment time? *(00:00-23:59)*	17:44 (24 HR)
Treatment Date and Time (derived)	3 AUG 2020 17:44
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-6153860

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	3 AUG 2020
Collection time *(00:00-23:59)*	17:24 (24 HR)
Collection date and time (derived)	3 AUG 2020 17:24

FDA-CBER-2022-1614-6153861

Collection date *(dd MMM yyyy)*			3 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:18	3 AUG 2020 17:18
Nasopharyngeal Swab 2	Yes	17:18	3 AUG 2020 17:18

FDA-CBER-2022-1614-6153862

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

FDA-CBER-2022-1614-6153863

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:11:02

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**	97.9 °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):	
To **TREAT** pain or fever that has already occurred	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	03 AUG 2020 18:17
PC Open Date & Time	03 AUG 2020 18:04
PC Close Date & Time	03 AUG 2020 20:34

FDA-CBER-2022-1614-6153864

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:11:02

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**	98.2 °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):	
To **TREAT** pain or fever that has already occurred	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	03 AUG 2020 21:36
PC Open Date & Time	03 AUG 2020 21:29
PC Close Date & Time	04 AUG 2020 11:59

FDA-CBER-2022-1614-6153865

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:11:02

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):	
To **TREAT** pain or fever that has already occurred	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	04 AUG 2020 12:03
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

FDA-CBER-2022-1614-6153866

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ○
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	05 AUG 2020 12:07
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

FDA-CBER-2022-1614-6153867

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ○
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	06 AUG 2020 12:03
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

FDA-CBER-2022-1614-6153868

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:11:02

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**	98.2 °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):	
To **TREAT** pain or fever that has already occurred	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	07 AUG 2020 12:14
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

FDA-CBER-2022-1614-6153869

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	08 AUG 2020 12:42
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

FDA-CBER-2022-1614-6153870

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	09 AUG 2020 12:02
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

FDA-CBER-2022-1614-6153871

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 8

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	10 AUG 2020 12:14
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

FDA-CBER-2022-1614-6153872

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(9)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 9

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

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

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

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

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

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

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

FDA-CBER-2022-1614-6153873

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 10

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	12 AUG 2020 13:01
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

FDA-CBER-2022-1614-6153874

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 11

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	13 AUG 2020 12:32
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

FDA-CBER-2022-1614-6153875

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 12

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):	
To **TREAT** pain or fever that has already occurred	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	14 AUG 2020 12:13
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

FDA-CBER-2022-1614-6153876

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 13

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ○
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	15 AUG 2020 12:05
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

FDA-CBER-2022-1614-6153877

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 14

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ○
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	16 AUG 2020 12:05
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

FDA-CBER-2022-1614-6153878

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 15

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):	
To **TREAT** pain or fever that has already occurred	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	17 AUG 2020 12:46
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

FDA-CBER-2022-1614-6153879

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 16

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	18 AUG 2020 12:17
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

FDA-CBER-2022-1614-6153880

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	03 AUG 2020 18:18
PC Open Date & Time	03 AUG 2020 18:04
PC Close Date & Time	03 AUG 2020 20:34

FDA-CBER-2022-1614-6153881

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:11:02

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	03 AUG 2020 21:37
PC Open Date & Time	03 AUG 2020 21:29
PC Close Date & Time	04 AUG 2020 11:59

FDA-CBER-2022-1614-6153882

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:11:02

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	04 AUG 2020 12:03
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

FDA-CBER-2022-1614-6153883

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:11:02

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	05 AUG 2020 12:07
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

FDA-CBER-2022-1614-6153884

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:11:02

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	06 AUG 2020 12:03
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

FDA-CBER-2022-1614-6153885

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:11:02

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	07 AUG 2020 12:15
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

FDA-CBER-2022-1614-6153886

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:11:02

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	08 AUG 2020 12:42
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

FDA-CBER-2022-1614-6153887

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:11:02

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	09 AUG 2020 12:03
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

FDA-CBER-2022-1614-6153888

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-2022-1614-6153889

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	03 AUG 2020 18:19
PC Open Date & Time	03 AUG 2020 18:04
PC Close Date & Time	03 AUG 2020 20:34

FDA-CBER-2022-1614-6153890

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-2022-1614-6153891

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ◉ Yes ○
PC Time stamp	03 AUG 2020 21:37
PC Open Date & Time	03 AUG 2020 21:29
PC Close Date & Time	04 AUG 2020 11:59

FDA-CBER-2022-1614-6153892

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02

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-2022-1614-6153893

	Yes ☐
PC Time stamp	04 AUG 2020 12:04
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02

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-2022-1614-6153895

	Yes ☐
PC Time stamp	05 AUG 2020 12:08
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02

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-2022-1614-6153897

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02

	Yes ☐
PC Time stamp	06 AUG 2020 12:03
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

FDA-CBER-2022-1614-6153898

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02

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-2022-1614-6153899

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02

	Yes ☐
PC Time stamp	07 AUG 2020 12:15
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

FDA-CBER-2022-1614-6153900

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02

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-2022-1614-6153901

	Yes ☐
PC Time stamp	08 AUG 2020 12:43
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02

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-2022-1614-6153903

	Yes ☐
PC Time stamp	09 AUG 2020 12:03
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	10 AUG 2020 12:14
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

FDA-CBER-2022-1614-6153905

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6153906

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 10
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	12 AUG 2020 13:01
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

FDA-CBER-2022-1614-6153907

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 11
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	13 AUG 2020 12:32
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

FDA-CBER-2022-1614-6153908

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(12)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 12
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	14 AUG 2020 12:14
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

FDA-CBER-2022-1614-6153909

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(13)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	15 AUG 2020 12:05
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

FDA-CBER-2022-1614-6153910

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(14)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 14
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	16 AUG 2020 12:05
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

FDA-CBER-2022-1614-6153911

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(15)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 15
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	17 AUG 2020 12:46
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

FDA-CBER-2022-1614-6153912

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(16)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 16
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	18 AUG 2020 12:17
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

FDA-CBER-2022-1614-6153913

US3722066
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	10 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-2022-1614-6153914

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

FDA-CBER-2022-1614-6153915

US3722066
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	18 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-2022-1614-6153916

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

FDA-CBER-2022-1614-6153917

US3722066
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02

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-2022-1614-6153918

US3722066
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6153919

US3722066
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-6153920

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	28 AUG 2020
Time of assessment *(00:00-23:59)*	10:35 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 10:35
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	71 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	83 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-6153921

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	28 AUG 2020
Time of assessment *(00:00-23:59)*	12:21 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 12:21
Temperature *(xxx.x)*	97.5 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	76 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	89 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-6153922

US3722066
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:11:02

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	28 AUG 2020

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

FDA-CBER-2022-1614-6153923

US3722066
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:11:02

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)*	28 AUG 2020
What was the treatment time? *(00:00-23:59)*	11:51 (24 HR)
Treatment Date and Time (derived)	28 AUG 2020 11:51
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-2022-1614-6153924

US3722066
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:11:02

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	28 AUG 2020
Collection time *(00:00-23:59)*	11:25 (24 HR)
Collection date and time (derived)	28 AUG 2020 11:25

FDA-CBER-2022-1614-6153925

Collection date *(dd MMM yyyy)*			28 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:57	28 AUG 2020 10:57
Nasopharyngeal Swab 2	Yes	10:57	28 AUG 2020 10:57

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

FDA-CBER-2022-1614-6153927

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:11:02

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**	97.5 °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	28 AUG 2020 12:21
PC Open Date & Time	28 AUG 2020 12:11
PC Close Date & Time	28 AUG 2020 14:41

FDA-CBER-2022-1614-6153928

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:11:02

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**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	28 AUG 2020 15:50
PC Open Date & Time	28 AUG 2020 15:36
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-6153929

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.9 °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	29 AUG 2020 21:06
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

FDA-CBER-2022-1614-6153930

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.5 °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	30 AUG 2020 13:46
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

FDA-CBER-2022-1614-6153931

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.6 °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	31 AUG 2020 12:04
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

FDA-CBER-2022-1614-6153932

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	01 SEP 2020 12:02
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

FDA-CBER-2022-1614-6153933

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	02 SEP 2020 12:03
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

FDA-CBER-2022-1614-6153934

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.5 °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	03 SEP 2020 12:06
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-6153935

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	28 AUG 2020 12:22
PC Open Date & Time	28 AUG 2020 12:11
PC Close Date & Time	28 AUG 2020 14:41

FDA-CBER-2022-1614-6153936

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:11:02

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	28 AUG 2020 15:51
PC Open Date & Time	28 AUG 2020 15:36
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-6153937

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:11:02

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	29 AUG 2020 21:06
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

FDA-CBER-2022-1614-6153938

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:11:02

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	30 AUG 2020 13:46
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

FDA-CBER-2022-1614-6153939

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:11:02

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	31 AUG 2020 12:04
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

FDA-CBER-2022-1614-6153940

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:11:02

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	01 SEP 2020 12:02
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

FDA-CBER-2022-1614-6153941

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6153942

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:11:02

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	03 SEP 2020 12:06
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-6153943

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-2022-1614-6153944

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ◉ Yes ○
PC Time stamp	28 AUG 2020 12:23
PC Open Date & Time	28 AUG 2020 12:11
PC Close Date & Time	28 AUG 2020 14:41

FDA-CBER-2022-1614-6153945

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-2022-1614-6153946

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	28 AUG 2020 15:51
PC Open Date & Time	28 AUG 2020 15:36
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-6153947

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02

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-2022-1614-6153948

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02

	Yes ☐
PC Time stamp	29 AUG 2020 21:06
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

FDA-CBER-2022-1614-6153949

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02

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-2022-1614-6153950

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02

	Yes ☐
PC Time stamp	30 AUG 2020 13:46
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

FDA-CBER-2022-1614-6153951

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02

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-2022-1614-6153952

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02

	Yes ☐
PC Time stamp	31 AUG 2020 12:04
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

FDA-CBER-2022-1614-6153953

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02

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-2022-1614-6153954

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02

	Yes ☐
PC Time stamp	01 SEP 2020 12:02
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

FDA-CBER-2022-1614-6153955

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-2022-1614-6153956

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

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02

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-2022-1614-6153958

	Yes ☐
PC Time stamp	03 SEP 2020 12:06
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3722066
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	7 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-2022-1614-6153960

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

FDA-CBER-2022-1614-6153961

US3722066
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	11 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-2022-1614-6153962

US3722066
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6153963

US3722066
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	18 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-2022-1614-6153964

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

FDA-CBER-2022-1614-6153965

US3722066
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	25 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT3

FDA-CBER-2022-1614-6153966

US3722066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	25 SEP 2020
Time of assessment *(00:00-23:59)*	09:01 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 09:01
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	69 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-6153967

US3722066
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:11:02

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	25 SEP 2020

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

FDA-CBER-2022-1614-6153968

US3722066
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:11:02

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	25 SEP 2020
Collection time *(00:00-23:59)*	09:38 (24 HR)
Collection date and time (derived)	25 SEP 2020 09:38

FDA-CBER-2022-1614-6153969

US3722066
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6153970

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 OCT 2020 11:19:27
Patient Cloud Open Date & Time	03 OCT 2020 00:01
Patient Cloud Close Date & Time	07 OCT 2020 23:59

FDA-CBER-2022-1614-6153971

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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	10 OCT 2020 00:07:39
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

FDA-CBER-2022-1614-6153972

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 OCT 2020 15:05:32
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

FDA-CBER-2022-1614-6153973

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 OCT 2020 02:13:34
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

FDA-CBER-2022-1614-6153974

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Have you been exposed to someone with known SARS-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):	
Fever (Temperature ≥ 100.4°F/38°C)	True
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Date and time of submission	14 NOV 2020 00:27:04
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

FDA-CBER-2022-1614-6153975

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2020 00:01
Patient Cloud Close Date & Time	04 OCT 2020 23:59

FDA-CBER-2022-1614-6153977

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2020 00:01
Patient Cloud Close Date & Time	11 OCT 2020 23:59

FDA-CBER-2022-1614-6153979

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 ☐

FDA-CBER-2022-1614-6153980

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

FDA-CBER-2022-1614-6153981

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

FDA-CBER-2022-1614-6153983

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

FDA-CBER-2022-1614-6153985

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

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

FDA-CBER-2022-1614-6153987

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 ☐

FDA-CBER-2022-1614-6153988

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

FDA-CBER-2022-1614-6153989

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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)	False
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Have 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 NOV 2020 09:00:32
Patient Cloud Open Date & Time	18 NOV 2020 00:01

FDA-CBER-2022-1614-6153990

Patient Cloud Close Date & Time	22 NOV 2020 23:59

FDA-CBER-2022-1614-6153991

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

FDA-CBER-2022-1614-6153993

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

FDA-CBER-2022-1614-6153995

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6153997

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 ☐

FDA-CBER-2022-1614-6153998

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

FDA-CBER-2022-1614-6153999

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154001

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

FDA-CBER-2022-1614-6154003

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 ☐

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

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154007

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 ☐

FDA-CBER-2022-1614-6154008

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154009

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154011

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 ☐

FDA-CBER-2022-1614-6154012

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154013

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154015

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154017

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154019

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 ☐

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

FDA-CBER-2022-1614-6154021

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154023

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154025

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 ☐

FDA-CBER-2022-1614-6154026

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154027

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 ☐

FDA-CBER-2022-1614-6154028

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154029

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154031

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 ☐

FDA-CBER-2022-1614-6154032

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154033

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154035

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	28 APR 2021 00:01
Patient Cloud Close Date & Time	02 MAY 2021 23:59

FDA-CBER-2022-1614-6154037

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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 ☐

FDA-CBER-2022-1614-6154038

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154039

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 ☐

FDA-CBER-2022-1614-6154040

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154041

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 ☐

FDA-CBER-2022-1614-6154042

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154043

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 ☐

FDA-CBER-2022-1614-6154044

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154045

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 ☐

FDA-CBER-2022-1614-6154046

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154047

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154049

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154051

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-2022-1614-6154052

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154053

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154055

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-6154056

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154057

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 ☐

FDA-CBER-2022-1614-6154058

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154059

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154061

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154063

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154065

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-2022-1614-6154066

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154067

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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 ☐

FDA-CBER-2022-1614-6154068

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154069

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 ☐

FDA-CBER-2022-1614-6154070

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154071

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-2022-1614-6154072

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154073

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-2022-1614-6154074

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154075

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-6154076

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154077

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 ☐

FDA-CBER-2022-1614-6154078

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154079

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 ☐

FDA-CBER-2022-1614-6154080

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2021 00:01
Patient Cloud Close Date & Time	03 OCT 2021 23:59

FDA-CBER-2022-1614-6154081

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154083

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-2022-1614-6154084

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154085

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 ☐

FDA-CBER-2022-1614-6154086

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154087

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154089

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154091

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-2022-1614-6154092

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154093

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154094

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154095

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 ☐

FDA-CBER-2022-1614-6154096

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154097

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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 ☐

FDA-CBER-2022-1614-6154098

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154099

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154101

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154103

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154105

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	29 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

FDA-CBER-2022-1614-6154107

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-2022-1614-6154108

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154109

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

FDA-CBER-2022-1614-6154110

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154111

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 ☐

FDA-CBER-2022-1614-6154112

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154113

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 ☐

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

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 ☐

FDA-CBER-2022-1614-6154116

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154117

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-2022-1614-6154118

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154119

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 ☐

FDA-CBER-2022-1614-6154120

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154121

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154123

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 ☐

FDA-CBER-2022-1614-6154124

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154125

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 ☐

FDA-CBER-2022-1614-6154126

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154127

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154129

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154131

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 ☐

FDA-CBER-2022-1614-6154132

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154133

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-2022-1614-6154134

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154135

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-2022-1614-6154136

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154137

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-2022-1614-6154138

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154139

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154141

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154143

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154145

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-2022-1614-6154146

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

FDA-CBER-2022-1614-6154147

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154149

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 ☐

FDA-CBER-2022-1614-6154150

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154151

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-2022-1614-6154152

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154153

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154155

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 ☐

FDA-CBER-2022-1614-6154156

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154157

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-2022-1614-6154158

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154159

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154161

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 ☐

FDA-CBER-2022-1614-6154162

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154163

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154165

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154167

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154169

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154171

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-2022-1614-6154172

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154173

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 ☐

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154175

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

FDA-CBER-2022-1614-6154176

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154177

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 ☐

FDA-CBER-2022-1614-6154178

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154179

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-2022-1614-6154180

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154181

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-2022-1614-6154182

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154183

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-2022-1614-6154184

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154185

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 ☐

FDA-CBER-2022-1614-6154186

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154187

US3722066
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	22 OCT 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-2022-1614-6154188

US3722066
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154189

US3722066
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	16 NOV 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	SUBJECT REPORTED SOB, FEVER OF 102.6 AND MUSCLE ACHES. SUBJECT HAS BEEN SCHEDULED FOR A SICK VISIT.

FDA-CBER-2022-1614-6154190

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

FDA-CBER-2022-1614-6154191

US3722066
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02

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-2022-1614-6154192

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

FDA-CBER-2022-1614-6154193

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: COVID-19 Contact
Generated On: 26 Nov 2020 11:11:02

Date of Contact	16 NOV 2020
Time of Contact	15:16
Date and Time of Contact (derived)	16 NOV 2020 15:16
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-2022-1614-6154194

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32
- Day 33

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02

	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	16 NOV 2020
Assessment Not Done	False
O2 Saturation	86 %
O2 Saturation Units	%
Temperature	98.7 F
Chills	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ■
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ■
	Not Done ☐
Fatigue	None ■

FDA-CBER-2022-1614-6154196

	Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Body Aches	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Headache	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nasal Congestion	None ■ Mild ☐ Moderate ☐

	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

FDA-CBER-2022-1614-6154198

Symptom Day

- [x] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [ ] Day 9
- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [ ] Day 19
- [ ] Day 20
- [ ] Day 21
- [ ] Day 22
- [ ] Day 23
- [ ] Day 24
- [ ] Day 25
- [ ] Day 26
- [ ] Day 27
- [ ] Day 28
- [ ] Day 29
- [ ] Day 30
- [ ] Day 31
- [ ] Day 32
- [ ] Day 33

FDA-CBER-2022-1614-6154199

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02

	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	11 NOV 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ■
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ■
	Not Done ☐
Fatigue	None ■

FDA-CBER-2022-1614-6154200

	Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Body Aches	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Headache	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nasal Congestion	None ■ Mild ☐ Moderate ☐

	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32
- Day 33

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02

	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	12 NOV 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ■
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ■
	Not Done ☐
Fatigue	None ■

FDA-CBER-2022-1614-6154204

	Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Body Aches	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Headache	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nasal Congestion	None ■ Mild ☐ Moderate ☐

	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

FDA-CBER-2022-1614-6154206

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32
- Day 33

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02

	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	13 NOV 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ■
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ■
	Not Done ☐
Fatigue	None ■

FDA-CBER-2022-1614-6154208

	Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Body Aches	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Headache	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nasal Congestion	None ■ Mild ☐ Moderate ☐

	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

FDA-CBER-2022-1614-6154210

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32
- Day 33

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02

	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	14 NOV 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ■
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ■
	Not Done ☐
Fatigue	None ■

FDA-CBER-2022-1614-6154212

	Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Body Aches	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Headache	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nasal Congestion	None ■ Mild ☐ Moderate ☐

	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32
- Day 33

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02

	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	15 NOV 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ■
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ■
	Not Done ☐
Fatigue	None ■

FDA-CBER-2022-1614-6154216

	Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Body Aches	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Headache	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nasal Congestion	None ■ Mild ☐ Moderate ☐

	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

FDA-CBER-2022-1614-6154218

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:11:02

Date of Visit	16 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ■ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ■ No ☐
Date of Test	16 NOV 2020
Type of Test Performed	Nasopharyngeal Swab ■ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ■
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	1

FDA-CBER-2022-1614-6154219

Did the subject have Respiratory Rates ≥ 30 per Minute?	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
Respiratory Rate	
Did the subject have Heart Rate ≥ 125 beats per minute	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
Heart Rate	
Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?	Yes ■ No ☐
If Yes, provide:	
Start Date	16 NOV 2020
End Date	16 NOV 2020
Oxygen Saturation	86 %
Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
PaO2	
Did the subject have Respiratory failure?	Yes ☐ No ■
Start Date	
Did the subject have Acute Respiratory Distress Syndrome (ARDS)?	Yes ☐ No ■
Start Date	

If Yes to either Did subject require any of the following:

FDA-CBER-2022-1614-6154220

Ventilator Support:

High-Flow Oxygen?	Yes ☐ No ■
Start Date	
End Date	
Non-Invasive Ventilation?	Yes ☐ No ■
Start Date	
End Date	
Mechanical Ventilation?	Yes ☐ No ■
Start Date	
End Date	
ECMO?	Yes ☐ No ■
Start Date	
End Date	

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg	Yes ☐ No ■
Start Date	
End Date	
Evidence of Shock Requires Vasopressors	Yes ☐ No ■
Start Date	
End Date	
Acute Renal Dysfunction?	Yes ☐ No ■
Start Date	
Hepatic Dysfunction?	Yes ☐ No ■
Start Date	

FDA-CBER-2022-1614-6154221

Neurologic Dysfunction?	Yes ☐ No ■
Start Date	
Evidence of Pneumonia:	
Clinical Evidence	Yes ■ No ☐
Date of Assessment	16 NOV 2020
Radiographical Evidence	Yes ☐ No ■
Date of Assessment	16 NOV 2020

Admission to an intensive care unit due to SARS-CoV-2	Yes ☐ No ■
Start Date	
End Date	

FDA-CBER-2022-1614-6154222

Generate Next COVID-19 Assessment	Yes ☐ No ☐

FDA-CBER-2022-1614-6154223

US3722066
Folder: Illness Visit (1)
Form: Saliva Collection
Generated On: 26 Nov 2020 11:11:02

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

FDA-CBER-2022-1614-6154224

US3722066
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	16 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SICKD1

FDA-CBER-2022-1614-6154225

US3722066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	16 NOV 2020
Time of assessment *(00:00-23:59)*	15:20 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 15:20
Height *(xxx.x)*	167 cm
Weight *(xxx.x)*	196 lb
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-6154226

US3722066
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:11:02

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

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

FDA-CBER-2022-1614-6154227

US3722066
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 26 Nov 2020 11:11:02

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ■ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	16 NOV 2020

FDA-CBER-2022-1614-6154228

US3722066
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02

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

FDA-CBER-2022-1614-6154229

US3722066
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02

Were vital signs assessed?	Yes ☐ No ☐
Date of assessment *(dd MMM yyyy)*	
Time of assessment *(00:00-23:59)*	
Vital Signs Date and Time (derived)	
Temperature *(xxx.x)*	
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	
Pulse units	
Respiratory Rate *(xxx)*	
Respiratory Rate units	
Systolic Blood Pressure *(xxx)*	
Systolic Blood Pressure units	
Diastolic Blood Pressure *(xxx)*	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-6154230

US3722066
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:11:02

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-2022-1614-6154231

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ☐ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	_____

US3722066
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 26 Nov 2020 11:11:02

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

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-6154233

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02

AEID	USA-US083-2020-MRNA-1273-P30 1000007
Adverse event	POSITIVE COVID 19
Was this a medically-attended AE?	Yes ■ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ■ No ☐
Start date *(dd MMM yyyy)*	11 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ■ No ☐
If not Ongoing, end date *(dd MMM yyyy)*	
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)*	16 NOV 2020
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ■ Unknown ☐
Number of Days in ICU	

FDA-CBER-2022-1614-6154234

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-2022-1614-6154235

SITE RECEIVED AN EMAIL ALERT ON 15NOV2020, STATING THAT THE SUBJECT HAD COVID 19 SYMPTOMS. SUBJECT WAS CALLED ON 16NOV2020 AT 08:49 AND AT THAT TIME HE STATED THEY HAD SOB, FEVER OF UP TO 102.6, CHILLS, AND MUSCLE ACHES. SUBJECT WAS ADVISED TO GO TO ER IN THE EVENT OF AN EMERGENCY. SUBJECT EXPRESSED HE JUST THOUGHT HE HAD PNEUMONIA. PER PROTOCOL, SUBJECT WAS SCHEDULED TO COME TO SITE FOR A CONVALESCENT VISIT. UPON ARRIVING THE SUBJECT STATED THAT THEY HAD RECEIVED THEIR TEST RESULTS BACK AND THAT THEY HAD TESTED POSITIVE FOR COVID 19. HIS O2 WAS 87% AT TIME OF VISIT AND THIS WAS CONFIRMED WITH A SECOND READING. THE SUB I ONSITE CONTACTED THE PI WHO ADVISED EMS TO BE CALLED FOR PATIENT TO GO TO THE ER. AT THAT TIME 911 WAS CALLED AND THE SUBJECT WAS TRANSPORTED TO THE ER. SUBJECT WAS TAKEN TO ST. FRANCES DOWNTOWN PER SUBJECT REQUEST. SITE WILL CONTINUE TO FOLLOW UP

FDA-CBER-2022-1614-6154236

	WITH SUBJECT AS REQUIRED PER PROTOCOL. SUBJECT CONFIRMED VIA PHONE HE WAS ADMITTED TO HOSPITAL ON 17 NOV 2020. SAE DOCUMENTED IN SOURCE AND SPONSOR NOTIFIED. SITE WILL CONTINUE TO FOLLOW PROGRESS OF PATIENT AND WILL GET A MEDICAL RECORDS RELEASE AS SOON AS POSSIBLE IN ORDER TO GET RECORDS.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 26 Nov 2020 11:11:02

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

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

FDA-CBER-2022-1614-6154238

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:11:02

Name of Medication	AMLODIPINE BESYLATE
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-2022-1614-6154239

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

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:11:02

Name of Medication	ATORVASTAIN
Prophylaxis	Yes ☐ No ■
Indication	HYPERCHOLESTEROLEMIA
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-2022-1614-6154241

	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 1990
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-2022-1614-6154242

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:11:02

Name of Medication	GABAPENTIN
Prophylaxis	Yes ☐ No ■
Indication	RESTLESS LEG SYNDROME
Dose per administration	1500
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-2022-1614-6154243

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

FDA-CBER-2022-1614-6154244

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 11:11:02

Name of Medication	INDAPAMIDE
Prophylaxis	Yes ☐ No ■
Indication	HYPERTENSION
Dose per administration	1.25
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

FDA-CBER-2022-1614-6154245

	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2019
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

FDA-CBER-2022-1614-6154246

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 11:11:02

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes ☐ No ■
Indication	HYPOTHYROIDISM
Dose per administration	.112
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-2022-1614-6154247

	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 1990
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-2022-1614-6154248

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 11:11:02

Name of Medication	OMEPRAZOLE
Prophylaxis	Yes ☐ No ■
Indication	GERD
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-2022-1614-6154249

	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 1990
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 ■

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 11:11:02

Name of Medication	ROPINIROLE
Prophylaxis	Yes ☐ No ■
Indication	RESTLESS LEG SYNDROME
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-2022-1614-6154251

	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2015
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

FDA-CBER-2022-1614-6154252

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 11:11:02

Name of Medication	VALSARTAN
Prophylaxis	Yes ☐ No ■
Indication	HYPERTENSION
Dose per administration	320
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-2022-1614-6154253

	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2016
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

FDA-CBER-2022-1614-6154254

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 11:11:02

Name of Medication	FLOVENT
Prophylaxis	Yes ☐ No ■
Indication	ASTHMA
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-2022-1614-6154255

	Respiratory (Inhalation) ■ Intralesional ☐ Intraperiteoneal ☐ Nasal ☐ Vaginal ☐ Rectal ☐ Intravenous ☐ Intravenous Bolus ☐ Intravenous Drip ☐ Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 1990
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

FDA-CBER-2022-1614-6154256

Name of Medication	IPRATROPIUM .006%
Prophylaxis	Yes ☐ No ■
Indication	RHINORRHEA
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	SPRAYS EACH NOSTRIL
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

	Respiratory (Inhalation) ☐ Intralesional ☐ Intraperiteoneal ☐ Nasal ■ Vaginal ☐ Rectal ☐ Intravenous ☐ Intravenous Bolus ☐ Intravenous Drip ☐ Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2019
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

FDA-CBER-2022-1614-6154258

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 11:11:02

Name of Medication	MONTELUKAST
Prophylaxis	Yes ☐ No ■
Indication	SEASONAL ALLERGIES
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-2022-1614-6154259

	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 1990
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-2022-1614-6154260

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 11:11:02

Name of Medication	ASPIRIN
Prophylaxis	Yes ■ No ☐
Indication	CARDIAC PROPHYLAXIS
Dose per administration	81
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

FDA-CBER-2022-1614-6154261

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

Name of Medication	FERROUS SULFATE
Prophylaxis	Yes ☐ No ■
Indication	IRON DEFICIENCY ANEMIA
Dose per administration	130
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 1995
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-2022-1614-6154264

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

	Respiratory (Inhalation) ☐ Intralesional ☐ Intraperiteoneal ☐ Nasal ☐ Vaginal ☐ Rectal ☐ Intravenous ☐ Intravenous Bolus ☐ Intravenous Drip ☐ Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

FDA-CBER-2022-1614-6154266

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 11:11:02

Name of Medication	CO-Q10
Prophylaxis	Yes ☐ No ■
Indication	SUPPLEMENT
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-2022-1614-6154267

	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

FDA-CBER-2022-1614-6154268

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 11:11:02

Name of Medication	VITAMIN D3
Prophylaxis	Yes ☐ No ■
Indication	SUPPLEMENT
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-2022-1614-6154269

	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2014
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 ■

US3722066
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 26 Nov 2020 11:11:02

Were any concomitant procedures performed?	Yes ☐ No ■

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-6154271

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify

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-2022-1614-6154273

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-2022-1614-6154274

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02

SAEID	USA-US083-2020-MRNA-1273-P301000007
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

FDA-CBER-2022-1614-6154275

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form (1)
Generated On: 26 Nov 2020 11:11:02

SAEID	USA-US083-2020-MRNA-1273-P301000007
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	18/NOV/2020 18:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-6154276

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form (2)
Generated On: 26 Nov 2020 11:11:02

SAEID	USA-US083-2020-MRNA-1273-P301000007
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	20/NOV/2020 16:05
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-2022-1614-6154277

Audit

US3722066 (Prod: Keystone VitaLink Research - Greenville - PPDS)

US3722066
Form: Participant Creation
Generated On: 26 Nov 2020 11:11:02
Participant ID

Audit	User	Time (GMT)
User entered 'US3722066'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 20:54:23

FDA-CBER-2022-1614-6154279

US3722066
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02
Was this visit performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:46:50

FDA-CBER-2022-1614-6154280

US3722066
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '03 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 20:54:24

FDA-CBER-2022-1614-6154281

US3722066
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:46:50

FDA-CBER-2022-1614-6154282

US3722066
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02
Folder OID

Audit	User	Time (GMT)
User entered 'SCRN'	System	03 Aug 2020 21:46:50

FDA-CBER-2022-1614-6154283

US3722066
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:11:02
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1952'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 20:54:25

FDA-CBER-2022-1614-6154284

US3722066
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:11:02
Age

Audit	User	Time (GMT)
User entered '67'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:06

FDA-CBER-2022-1614-6154285

US3722066
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:11:02
Age Units

Audit	User	Time (GMT)
User entered 'YEARS'	System	03 Aug 2020 21:47:06

FDA-CBER-2022-1614-6154286

US3722066
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:11:02
Age (Derived)

Audit	User	Time (GMT)
User entered '68'	System	03 Aug 2020 21:47:21

FDA-CBER-2022-1614-6154287

US3722066
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:11:02
Sex

Audit	User	Time (GMT)
User entered 'Male (M)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:06

FDA-CBER-2022-1614-6154288

US3722066
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:11:02
Ethnicity

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:06

FDA-CBER-2022-1614-6154289

US3722066
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:11:02
White

Audit	User	Time (GMT)
User entered '1'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:06

FDA-CBER-2022-1614-6154290

US3722066
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:11:02
Black

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:06

FDA-CBER-2022-1614-6154291

US3722066
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:11:02
Asian

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:06

FDA-CBER-2022-1614-6154292

US3722066
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:11:02
American Indian or Alaska Native

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:06

FDA-CBER-2022-1614-6154293

US3722066
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:11:02
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:06

FDA-CBER-2022-1614-6154294

US3722066
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:11:02
Other

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:06

FDA-CBER-2022-1614-6154295

US3722066
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:11:02
If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:06

FDA-CBER-2022-1614-6154296

US3722066
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:11:02
Unknown

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:06

FDA-CBER-2022-1614-6154297

US3722066
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:11:02
Not reported

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:06

FDA-CBER-2022-1614-6154298

US3722066
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:11:02
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '3 Aug 2020'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:21

FDA-CBER-2022-1614-6154299

US3722066
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:11:02
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	03 Aug 2020 21:47:21

FDA-CBER-2022-1614-6154300

US3722066
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:11:02
Year of Informed Consent (derived)

Audit	User	Time (GMT)
User entered '2020'	System	03 Aug 2020 21:47:21

FDA-CBER-2022-1614-6154301

US3722066
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:11:02
Protocol Version

Audit	User	Time (GMT)
User closed query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 19:56:12
Query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' answered with 'completed' (Site from DM).	Kayla Peay (b) (4) (b) (4)	17 Sep 2020 14:35:26
User entered 'Amendment 1 (1)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	17 Sep 2020 14:35:22
User opened query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 07:21:13
User entered 'Amendment 5 (5)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:21

FDA-CBER-2022-1614-6154302

US3722066
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:11:02
Was participant enrolled in the study?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:21

FDA-CBER-2022-1614-6154303

US3722066
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:11:02
If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:21

FDA-CBER-2022-1614-6154304

US3722066
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:11:02
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:21

FDA-CBER-2022-1614-6154305

US3722066
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:11:02
Was this participant screened previously?

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:21

FDA-CBER-2022-1614-6154306

US3722066
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:11:02
If Yes, previous participant number

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 20:54:24

FDA-CBER-2022-1614-6154307

US3722066
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:11:02
Enrollment Trigger

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 21:47:28

FDA-CBER-2022-1614-6154308

US3722066
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 26 Nov 2020 11:11:02
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:28

FDA-CBER-2022-1614-6154309

US3722066
Folder: Screening
Form: Medical History Summary
Generated On: 26 Nov 2020 11:11:02
Were any significant conditions reported?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:00:12

FDA-CBER-2022-1614-6154310

US3722066
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:11:02
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)	06 Aug 2020 13:02:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 13:02:20
Data point term sent to Coder	System	06 Aug 2020 13:01:08
User entered 'Hypertension'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:00:38

FDA-CBER-2022-1614-6154311

US3722066
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:11:02
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:00:38

FDA-CBER-2022-1614-6154312

US3722066
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:00:38

FDA-CBER-2022-1614-6154313

US3722066
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:11:02
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:00:38

FDA-CBER-2022-1614-6154314

US3722066
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:11:02
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:00:38

FDA-CBER-2022-1614-6154315

US3722066
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:11:02
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:00:38

FDA-CBER-2022-1614-6154316

US3722066
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:11:02
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	06 Aug 2020 13:00:38

FDA-CBER-2022-1614-6154317

US3722066
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:11:02
Start Year (derived)

Audit	User	Time (GMT)
User entered '2005'	System	06 Aug 2020 13:00:38

FDA-CBER-2022-1614-6154318

US3722066
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:11:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 13:00:38

FDA-CBER-2022-1614-6154319

US3722066
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:11:02
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 13:00:38

FDA-CBER-2022-1614-6154320

US3722066
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:11:02
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 20:39:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 20:39:02
Data point term sent to Coder	System	06 Aug 2020 13:01:09
User entered 'Hypercholesterol'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:01:07

FDA-CBER-2022-1614-6154321

US3722066
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:11:02
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 1990'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:01:07

FDA-CBER-2022-1614-6154322

US3722066
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:01:07

FDA-CBER-2022-1614-6154323

US3722066
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:11:02
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:01:07

FDA-CBER-2022-1614-6154324

US3722066
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:11:02
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:01:07

FDA-CBER-2022-1614-6154325

US3722066
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:11:02
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:01:07

FDA-CBER-2022-1614-6154326

US3722066
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:11:02
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	06 Aug 2020 13:01:07

FDA-CBER-2022-1614-6154327

US3722066
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:11:02
Start Year (derived)

Audit	User	Time (GMT)
User entered '1990'	System	06 Aug 2020 13:01:07

FDA-CBER-2022-1614-6154328

US3722066
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:11:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 13:01:07

FDA-CBER-2022-1614-6154329

US3722066
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:11:02
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 13:01:07

FDA-CBER-2022-1614-6154330

US3722066
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:11:02
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 13:03:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 13:03:07
Data point term sent to Coder	System	06 Aug 2020 13:02:10
User entered 'Restless leg syndrome'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:01:29

FDA-CBER-2022-1614-6154331

US3722066
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:11:02
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:01:29

FDA-CBER-2022-1614-6154332

US3722066
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:01:29

FDA-CBER-2022-1614-6154333

US3722066
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:11:02
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:01:29

FDA-CBER-2022-1614-6154334

US3722066
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:11:02
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:01:29

FDA-CBER-2022-1614-6154335

US3722066
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:11:02
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:01:29

FDA-CBER-2022-1614-6154336

US3722066
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:11:02
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	06 Aug 2020 13:01:29

FDA-CBER-2022-1614-6154337

US3722066
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:11:02
Start Year (derived)

Audit	User	Time (GMT)
User entered '2015'	System	06 Aug 2020 13:01:29

FDA-CBER-2022-1614-6154338

US3722066
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:11:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 13:01:29

FDA-CBER-2022-1614-6154339

US3722066
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:11:02
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 13:01:29

FDA-CBER-2022-1614-6154340

US3722066
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:11:02
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 13:03:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 13:03:07
Data point term sent to Coder	System	06 Aug 2020 13:02:10
User entered 'Hypothyroidism'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:01:50

FDA-CBER-2022-1614-6154341

US3722066
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:11:02
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 1990'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:01:50

FDA-CBER-2022-1614-6154342

US3722066
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:01:50

FDA-CBER-2022-1614-6154343

US3722066
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:11:02
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:01:50

FDA-CBER-2022-1614-6154344

US3722066
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:11:02
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:01:50

FDA-CBER-2022-1614-6154345

US3722066
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:11:02
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:01:50

FDA-CBER-2022-1614-6154346

US3722066
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:11:02
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	06 Aug 2020 13:01:50

FDA-CBER-2022-1614-6154347

US3722066
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:11:02
Start Year (derived)

Audit	User	Time (GMT)
User entered '1990'	System	06 Aug 2020 13:01:50

FDA-CBER-2022-1614-6154348

US3722066
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:11:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 13:01:50

FDA-CBER-2022-1614-6154349

US3722066
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:11:02
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 13:01:50

FDA-CBER-2022-1614-6154350

US3722066
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:11:02
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 13:03:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 13:03:07
Data point term sent to Coder	System	06 Aug 2020 13:02:10
User entered 'GERD'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:02:10

FDA-CBER-2022-1614-6154351

US3722066
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:11:02
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN Jul 1990'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:02:10

FDA-CBER-2022-1614-6154352

US3722066
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:02:10

FDA-CBER-2022-1614-6154353

US3722066
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:11:02
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:02:10

FDA-CBER-2022-1614-6154354

US3722066
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:11:02
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:02:10

FDA-CBER-2022-1614-6154355

US3722066
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:11:02
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:02:10

FDA-CBER-2022-1614-6154356

US3722066
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:11:02
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jul 1990'	System	06 Aug 2020 13:02:10

FDA-CBER-2022-1614-6154357

US3722066
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:11:02
Start Year (derived)

Audit	User	Time (GMT)
User entered '1990'	System	06 Aug 2020 13:02:10

FDA-CBER-2022-1614-6154358

US3722066
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:11:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 13:02:10

FDA-CBER-2022-1614-6154359

US3722066
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:11:02
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 13:02:10

FDA-CBER-2022-1614-6154360

US3722066
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 11:11:02
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 13:04:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 13:04:10
Data point term sent to Coder	System	06 Aug 2020 13:03:11
User entered 'Asthma'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:02:29

FDA-CBER-2022-1614-6154361

US3722066
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 11:11:02
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 1956'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:02:29

FDA-CBER-2022-1614-6154362

US3722066
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:02:29

FDA-CBER-2022-1614-6154363

US3722066
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 11:11:02
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:02:29

FDA-CBER-2022-1614-6154364

US3722066
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 11:11:02
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:02:29

FDA-CBER-2022-1614-6154365

US3722066
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 11:11:02
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:02:29

FDA-CBER-2022-1614-6154366

US3722066
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 11:11:02
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 1956'	System	06 Aug 2020 13:02:29

FDA-CBER-2022-1614-6154367

US3722066
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 11:11:02
Start Year (derived)

Audit	User	Time (GMT)
User entered '1956'	System	06 Aug 2020 13:02:29

FDA-CBER-2022-1614-6154368

US3722066
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 11:11:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 13:02:29

FDA-CBER-2022-1614-6154369

US3722066
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 11:11:02
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 13:02:29

FDA-CBER-2022-1614-6154370

US3722066
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 11:11:02
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 13:04:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 13:04:10
Data point term sent to Coder	System	06 Aug 2020 13:03:10
User entered 'Seasonal allergies'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:02:56

FDA-CBER-2022-1614-6154371

US3722066
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 11:11:02
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 1956'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:02:56

FDA-CBER-2022-1614-6154372

US3722066
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:02:56

FDA-CBER-2022-1614-6154373

US3722066
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 11:11:02
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:02:56

FDA-CBER-2022-1614-6154374

US3722066
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 11:11:02
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:02:56

FDA-CBER-2022-1614-6154375

US3722066
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 11:11:02
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:02:56

FDA-CBER-2022-1614-6154376

US3722066
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 11:11:02
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 1956'	System	06 Aug 2020 13:02:56

FDA-CBER-2022-1614-6154377

US3722066
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 11:11:02
Start Year (derived)

Audit	User	Time (GMT)
User entered '1956'	System	06 Aug 2020 13:02:56

FDA-CBER-2022-1614-6154378

US3722066
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 11:11:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 13:02:56

FDA-CBER-2022-1614-6154379

US3722066
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 11:11:02
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 13:02:56

FDA-CBER-2022-1614-6154380

US3722066
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 11:11:02
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalised osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:46:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:46:58
User closed query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 18:54:33
Data point term sent to Coder	System	25 Sep 2020 13:25:13
Query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate. ' answered with 'updated' (Site from DM).	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:24:44
Coding entries removed.	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:24:39
User entered 'OSTEOARTHRITIS in right knee and hip, bilateral thumbs and shoulders' reason for change: Per Query Resolution	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:24:39
User opened query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 11:57:31
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 13:05:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 13:05:18
Data point term sent to Coder	System	06 Aug 2020 13:04:11
User entered 'Osteoarthritis'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:03:46

FDA-CBER-2022-1614-6154381

US3722066
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 11:11:02
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 1990'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:03:46

FDA-CBER-2022-1614-6154382

US3722066
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:03:46

FDA-CBER-2022-1614-6154383

US3722066
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 11:11:02
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:03:46

FDA-CBER-2022-1614-6154384

US3722066
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 11:11:02
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:03:46

FDA-CBER-2022-1614-6154385

US3722066
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 11:11:02
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:03:46

FDA-CBER-2022-1614-6154386

US3722066
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 11:11:02
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	06 Aug 2020 13:03:46

FDA-CBER-2022-1614-6154387

US3722066
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 11:11:02
Start Year (derived)

Audit	User	Time (GMT)
User entered '1990'	System	06 Aug 2020 13:03:46

FDA-CBER-2022-1614-6154388

US3722066
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 11:11:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 13:03:46

FDA-CBER-2022-1614-6154389

US3722066
Folder: Screening
Form: Medical History (9)
Generated On: 26 Nov 2020 11:11:02
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 13:03:46

FDA-CBER-2022-1614-6154390

US3722066
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 11:11:02
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:19:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:19:12
Data point term sent to Coder	System	06 Aug 2020 13:05:14
User entered 'Tore rotator cuff left shoulder'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:04:27

FDA-CBER-2022-1614-6154391

US3722066
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 11:11:02
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 1972'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:04:27

FDA-CBER-2022-1614-6154392

US3722066
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:04:27

FDA-CBER-2022-1614-6154393

US3722066
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 11:11:02
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:04:27

FDA-CBER-2022-1614-6154394

US3722066
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 11:11:02
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:04:27

FDA-CBER-2022-1614-6154395

US3722066
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 11:11:02
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:04:27

FDA-CBER-2022-1614-6154396

US3722066
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 11:11:02
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 1972'	System	06 Aug 2020 13:04:27

FDA-CBER-2022-1614-6154397

US3722066
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 11:11:02
Start Year (derived)

Audit	User	Time (GMT)
User entered '1972'	System	06 Aug 2020 13:04:27

FDA-CBER-2022-1614-6154398

US3722066
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 11:11:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	06 Aug 2020 13:04:27

FDA-CBER-2022-1614-6154399

US3722066
Folder: Screening
Form: Medical History (10)
Generated On: 26 Nov 2020 11:11:02
Stop Year (derived)

Audit	User	Time (GMT)
User entered '2017'	System	06 Aug 2020 13:04:27

FDA-CBER-2022-1614-6154400

US3722066
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 11:11:02
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:19:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:19:13
Data point term sent to Coder	System	06 Aug 2020 13:05:14
User entered 'Tore rotator cuff right shoulder'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:05:10

FDA-CBER-2022-1614-6154401

US3722066
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 11:11:02
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 1972'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:05:10

FDA-CBER-2022-1614-6154402

US3722066
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:05:10

FDA-CBER-2022-1614-6154403

US3722066
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 11:11:02
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:05:10

FDA-CBER-2022-1614-6154404

US3722066
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 11:11:02
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:05:10

FDA-CBER-2022-1614-6154405

US3722066
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 11:11:02
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:05:10

FDA-CBER-2022-1614-6154406

US3722066
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 11:11:02
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 1972'	System	06 Aug 2020 13:05:10

FDA-CBER-2022-1614-6154407

US3722066
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 11:11:02
Start Year (derived)

Audit	User	Time (GMT)
User entered '1972'	System	06 Aug 2020 13:05:10

FDA-CBER-2022-1614-6154408

US3722066
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 11:11:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	06 Aug 2020 13:05:10

FDA-CBER-2022-1614-6154409

US3722066
Folder: Screening
Form: Medical History (11)
Generated On: 26 Nov 2020 11:11:02
Stop Year (derived)

Audit	User	Time (GMT)
User entered '2015'	System	06 Aug 2020 13:05:10

FDA-CBER-2022-1614-6154410

US3722066
Folder: Screening
Form: Medical History (12)
Generated On: 26 Nov 2020 11:11:02
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Abdominal hernias NEC, PT: Abdominal hernia, LLT: Abdominal hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 13:07:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 13:07:17
Data point term sent to Coder	System	06 Aug 2020 13:06:15
User entered 'Abdominal hernia'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:05:40

FDA-CBER-2022-1614-6154411

US3722066
Folder: Screening
Form: Medical History (12)
Generated On: 26 Nov 2020 11:11:02
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2006'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:05:40

FDA-CBER-2022-1614-6154412

US3722066
Folder: Screening
Form: Medical History (12)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:05:40

FDA-CBER-2022-1614-6154413

US3722066
Folder: Screening
Form: Medical History (12)
Generated On: 26 Nov 2020 11:11:02
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:05:40

FDA-CBER-2022-1614-6154414

US3722066
Folder: Screening
Form: Medical History (12)
Generated On: 26 Nov 2020 11:11:02
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2006'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:05:40

FDA-CBER-2022-1614-6154415

US3722066
Folder: Screening
Form: Medical History (12)
Generated On: 26 Nov 2020 11:11:02
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:05:40

FDA-CBER-2022-1614-6154416

US3722066
Folder: Screening
Form: Medical History (12)
Generated On: 26 Nov 2020 11:11:02
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	06 Aug 2020 13:05:40

FDA-CBER-2022-1614-6154417

US3722066
Folder: Screening
Form: Medical History (12)
Generated On: 26 Nov 2020 11:11:02
Start Year (derived)

Audit	User	Time (GMT)
User entered '2006'	System	06 Aug 2020 13:05:40

FDA-CBER-2022-1614-6154418

US3722066
Folder: Screening
Form: Medical History (12)
Generated On: 26 Nov 2020 11:11:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	06 Aug 2020 13:05:40

FDA-CBER-2022-1614-6154419

US3722066
Folder: Screening
Form: Medical History (12)
Generated On: 26 Nov 2020 11:11:02
Stop Year (derived)

Audit	User	Time (GMT)
User entered '2006'	System	06 Aug 2020 13:05:40

FDA-CBER-2022-1614-6154420

US3722066
Folder: Screening
Form: Medical History (13)
Generated On: 26 Nov 2020 11:11:02
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:03:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:03:44
Data point term sent to Coder	System	24 Sep 2020 21:03:00
User entered 'vasectomy'	Kayla Peay (b) (4) (b) (4)	24 Sep 2020 21:02:56

FDA-CBER-2022-1614-6154421

US3722066
Folder: Screening
Form: Medical History (13)
Generated On: 26 Nov 2020 11:11:02
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un UNK 1988'	Kayla Peay (b) (4) (b) (4)	24 Sep 2020 21:02:56

FDA-CBER-2022-1614-6154422

US3722066
Folder: Screening
Form: Medical History (13)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	24 Sep 2020 21:02:56

FDA-CBER-2022-1614-6154423

US3722066
Folder: Screening
Form: Medical History (13)
Generated On: 26 Nov 2020 11:11:02
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	24 Sep 2020 21:02:56

FDA-CBER-2022-1614-6154424

US3722066
Folder: Screening
Form: Medical History (13)
Generated On: 26 Nov 2020 11:11:02
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	24 Sep 2020 21:02:56

FDA-CBER-2022-1614-6154425

US3722066
Folder: Screening
Form: Medical History (13)
Generated On: 26 Nov 2020 11:11:02
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	24 Sep 2020 21:02:56

FDA-CBER-2022-1614-6154426

US3722066
Folder: Screening
Form: Medical History (13)
Generated On: 26 Nov 2020 11:11:02
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 1988'	System	24 Sep 2020 21:02:56

FDA-CBER-2022-1614-6154427

US3722066
Folder: Screening
Form: Medical History (13)
Generated On: 26 Nov 2020 11:11:02
Start Year (derived)

Audit	User	Time (GMT)
User entered '1988'	System	24 Sep 2020 21:02:56

FDA-CBER-2022-1614-6154428

US3722066
Folder: Screening
Form: Medical History (13)
Generated On: 26 Nov 2020 11:11:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
Query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 22:13:27
User opened query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 12:37:25
User entered empty.	System	24 Sep 2020 21:02:56

FDA-CBER-2022-1614-6154429

US3722066
Folder: Screening
Form: Medical History (13)
Generated On: 26 Nov 2020 11:11:02
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:02:56

FDA-CBER-2022-1614-6154430

US3722066
Folder: Screening
Form: Medical History (14)
Generated On: 26 Nov 2020 11:11:02
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemia deficiencies, PT: Iron deficiency anaemia, LLT: Iron deficiency anemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:30:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:30:40
Data point term sent to Coder	System	21 Oct 2020 17:29:43
User entered 'IRON DEFICIENCY ANEMIA'	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:29:42

FDA-CBER-2022-1614-6154431

US3722066
Folder: Screening
Form: Medical History (14)
Generated On: 26 Nov 2020 11:11:02
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 1995'	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:29:42

FDA-CBER-2022-1614-6154432

US3722066
Folder: Screening
Form: Medical History (14)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:29:42

FDA-CBER-2022-1614-6154433

US3722066
Folder: Screening
Form: Medical History (14)
Generated On: 26 Nov 2020 11:11:02
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:29:42

FDA-CBER-2022-1614-6154434

US3722066
Folder: Screening
Form: Medical History (14)
Generated On: 26 Nov 2020 11:11:02
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:29:42

FDA-CBER-2022-1614-6154435

US3722066
Folder: Screening
Form: Medical History (14)
Generated On: 26 Nov 2020 11:11:02
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:29:42

FDA-CBER-2022-1614-6154436

US3722066
Folder: Screening
Form: Medical History (14)
Generated On: 26 Nov 2020 11:11:02
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	21 Oct 2020 17:29:42

FDA-CBER-2022-1614-6154437

US3722066
Folder: Screening
Form: Medical History (14)
Generated On: 26 Nov 2020 11:11:02
Start Year (derived)

Audit	User	Time (GMT)
User entered '1995'	System	21 Oct 2020 17:29:42

FDA-CBER-2022-1614-6154438

US3722066
Folder: Screening
Form: Medical History (14)
Generated On: 26 Nov 2020 11:11:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:29:42

FDA-CBER-2022-1614-6154439

US3722066
Folder: Screening
Form: Medical History (14)
Generated On: 26 Nov 2020 11:11:02
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:29:42

FDA-CBER-2022-1614-6154440

US3722066
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:06:53

FDA-CBER-2022-1614-6154441

US3722066
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '3 Aug 2020'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:06:53

FDA-CBER-2022-1614-6154442

US3722066
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '17:11'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:06:53

FDA-CBER-2022-1614-6154443

US3722066
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '3 Aug 2020 17:11'	System	06 Aug 2020 13:06:53

FDA-CBER-2022-1614-6154444

US3722066
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Height *(xxx.x)*

Audit	User	Time (GMT)
User entered '167' cm	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:06:53
DataPoint set to visible.	System	03 Aug 2020 21:47:28

FDA-CBER-2022-1614-6154445

US3722066
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Weight *(xxx.x)*

Audit	User	Time (GMT)
User entered '88.9' kg	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:06:53
DataPoint set to visible.	System	03 Aug 2020 21:47:28

FDA-CBER-2022-1614-6154446

US3722066
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
BMI *(xxx.x)*

Audit	User	Time (GMT)
Amendment Manager: User entered '31.87637'	System	16 Sep 2020 23:41:47
User entered '31.9'	System	06 Aug 2020 13:06:53
DataPoint set to visible.	System	03 Aug 2020 21:47:28

FDA-CBER-2022-1614-6154447

US3722066
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
BMI units

Audit	User	Time (GMT)
User entered 'kg/m2'	System	06 Aug 2020 13:06:53
DataPoint set to visible.	System	03 Aug 2020 21:47:28

FDA-CBER-2022-1614-6154448

US3722066
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 14:41:29
User entered '98.6' F	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:06:53

FDA-CBER-2022-1614-6154449

US3722066
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Route of measurement

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 14:41:29
User entered 'Oral (Oral)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:06:53

FDA-CBER-2022-1614-6154450

US3722066
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
If Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:06:53

FDA-CBER-2022-1614-6154451

US3722066
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Pulse *(xxx)*

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 14:41:29
User entered '77'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:06:53

FDA-CBER-2022-1614-6154452

US3722066
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Aug 2020 13:06:53

FDA-CBER-2022-1614-6154453

US3722066
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 14:41:29
User entered '16'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:06:53

FDA-CBER-2022-1614-6154454

US3722066
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Aug 2020 13:06:53

FDA-CBER-2022-1614-6154455

US3722066
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 14:41:29
User entered '130'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:06:53

FDA-CBER-2022-1614-6154456

US3722066
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Aug 2020 13:06:53

FDA-CBER-2022-1614-6154457

US3722066
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 14:41:29
User entered '81'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:06:53

FDA-CBER-2022-1614-6154458

US3722066
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Aug 2020 13:06:53

FDA-CBER-2022-1614-6154459

US3722066
Folder: Screening
Form: Physical Examination
Generated On: 26 Nov 2020 11:11:02
Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:05

FDA-CBER-2022-1614-6154460

US3722066
Folder: Screening
Form: Physical Examination
Generated On: 26 Nov 2020 11:11:02
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)	06 Sep 2020 14:12:33
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 16:19:29
User entered '3 Aug 2020'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:05

FDA-CBER-2022-1614-6154461

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154462

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154463

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
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)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154464

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154465

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154466

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154467

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
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)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154468

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
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)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154469

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154470

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
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)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154471

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154472

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
Other

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154473

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
Specify

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154474

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154475

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154476

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
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'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154477

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154478

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
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'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154479

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
User entered '1'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154480

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
Other

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154481

US3722066
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:11:02
Specify

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

FDA-CBER-2022-1614-6154482

US3722066
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02
Was this visit performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:35

FDA-CBER-2022-1614-6154483

US3722066
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '3 Aug 2020'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:35

FDA-CBER-2022-1614-6154484

US3722066
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:35

FDA-CBER-2022-1614-6154485

US3722066
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02
Folder OID

Audit	User	Time (GMT)
User entered 'VISIT1'	System	03 Aug 2020 21:48:35

FDA-CBER-2022-1614-6154486

US3722066
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 11:11:02
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '03 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 21:24:10

FDA-CBER-2022-1614-6154487

US3722066
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 11:11:02
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 01:50:15
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:50:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Aug 2020 21:24:10
User entered '184495' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 21:24:10

FDA-CBER-2022-1614-6154488

US3722066
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 11:11:02
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 21:24:10

FDA-CBER-2022-1614-6154489

US3722066
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 11:11:02
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 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:51

FDA-CBER-2022-1614-6154490

US3722066
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 11:11:02

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:51

FDA-CBER-2022-1614-6154491

US3722066
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 11:11:02
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:51

FDA-CBER-2022-1614-6154492

US3722066
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 11:11:02
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:51

FDA-CBER-2022-1614-6154493

US3722066
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 11:11:02
Liver Disease

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:51

FDA-CBER-2022-1614-6154494

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 11:11:02
Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 14:41:38
User entered '167' cm reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154495

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 11:11:02
Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 14:41:38
User entered '196' lb reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154496

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 11:11:02
Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 14:41:38
User entered '167' cm reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154497

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 11:11:02
Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 14:41:38
User entered '196' lb reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154498

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154499

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154500

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '3 Aug 2020' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154501

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '17:09' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154502

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '3 Aug 2020 17:09'	System	11 Aug 2020 15:18:23
User entered empty.	System	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154503

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User entered '98.6' F reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154504

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Route of measurement

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154505

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
If Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154506

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Pulse *(xxx)*

Audit	User	Time (GMT)
User entered '77' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154507

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 15:18:23
User entered empty.	System	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154508

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User entered '16' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154509

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 15:18:23
User entered empty.	System	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154510

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '130' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154511

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 15:18:23
User entered empty.	System	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154512

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '81' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154513

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 15:18:23
User entered empty.	System	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154514

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 11:11:02
Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 14:41:38
User entered '167' cm reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154515

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 11:11:02
Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 14:41:38
User entered '196' lb reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154516

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154517

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154518

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '3 Aug 2020' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154519

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
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)	18 Aug 2020 12:46:21
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	11 Aug 2020 15:18:23
User entered '18:14' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '3 Aug 2020 18:14'	System	11 Aug 2020 15:18:23
User entered empty.	System	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154521

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User entered '97.9' F reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154522

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Route of measurement

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154523

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
If Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154524

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Pulse *(xxx)*

Audit	User	Time (GMT)
User entered '72' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154525

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 15:18:23
User entered empty.	System	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154526

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User entered '16' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154527

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 15:18:23
User entered empty.	System	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154528

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '128' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154529

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 15:18:23
User entered empty.	System	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154530

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '81' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154531

US3722066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 15:18:23
User entered empty.	System	06 Aug 2020 13:07:21

FDA-CBER-2022-1614-6154532

US3722066
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 26 Nov 2020 11:11:02
Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 14:41:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:34
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:24

FDA-CBER-2022-1614-6154533

US3722066
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 26 Nov 2020 11:11:02
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 14:41:45
User entered '3 Aug 2020' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:34
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:24

FDA-CBER-2022-1614-6154534

US3722066
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:11:02
Was study treatment given?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154535

US3722066
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:11:02
If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154536

US3722066
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:11:02
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154537

US3722066
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:11:02
What was the study treatment?

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154538

US3722066
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:11:02
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '3 Aug 2020'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154539

US3722066
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:11:02
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '17:44'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154540

US3722066
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:11:02
Treatment Date and Time (derived)

Audit	User	Time (GMT)
User entered '3 Aug 2020 17:44'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154541

US3722066
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:11:02
Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154542

US3722066
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:11:02
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154543

US3722066
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:11:02
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154544

US3722066
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:11:02
Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:47

FDA-CBER-2022-1614-6154545

US3722066
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:11:02
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '3 Aug 2020'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:47

FDA-CBER-2022-1614-6154546

US3722066
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:11:02
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '17:24'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:47

FDA-CBER-2022-1614-6154547

US3722066
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:11:02
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '3 Aug 2020 17:24'	System	06 Aug 2020 13:07:47

FDA-CBER-2022-1614-6154548

US3722066
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 26 Nov 2020 11:11:02
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '3 Aug 2020'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:08:01

FDA-CBER-2022-1614-6154549

US3722066
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 11:11:02
Lab Test

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:08:01

FDA-CBER-2022-1614-6154550

US3722066
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 11:11:02
Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:08:01

FDA-CBER-2022-1614-6154551

US3722066
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 11:11:02
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
User entered '17:18'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:08:01

FDA-CBER-2022-1614-6154552

US3722066
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 11:11:02
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '3 Aug 2020 17:18'	System	06 Aug 2020 13:08:01

FDA-CBER-2022-1614-6154553

US3722066
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 11:11:02
Lab Test

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:08:01

FDA-CBER-2022-1614-6154554

US3722066
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 11:11:02
Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:08:01

FDA-CBER-2022-1614-6154555

US3722066
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 11:11:02
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
User entered '17:18'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:08:01

FDA-CBER-2022-1614-6154556

US3722066
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 11:11:02
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '3 Aug 2020 17:18'	System	06 Aug 2020 13:08:01

FDA-CBER-2022-1614-6154557

US3722066
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:08:04

FDA-CBER-2022-1614-6154558

US3722066
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 13:08:04

FDA-CBER-2022-1614-6154559

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154560

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:16:24', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92b26b3d-c534-4d14-a1cf-85a0edd7c874'	System	03 Aug 2020 22:17:06
User entered 'Yes (Y)'	System	03 Aug 2020 22:17:06

FDA-CBER-2022-1614-6154561

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:16:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92b26b3d-c534-4d14-a1cf-85a0edd7c874'	System	03 Aug 2020 22:17:06
User entered '97.9'	System	03 Aug 2020 22:17:06

FDA-CBER-2022-1614-6154562

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:16:40', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92b26b3d-c534-4d14-a1cf-85a0edd7c874'	System	03 Aug 2020 22:17:06
User entered 'Yes (Y)'	System	03 Aug 2020 22:17:06

FDA-CBER-2022-1614-6154563

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:16:55', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92b26b3d-c534-4d14-a1cf-85a0edd7c874'	System	03 Aug 2020 22:17:06
User entered '0'	System	03 Aug 2020 22:17:06

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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)	18 Aug 2020 13:56:20
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Amy Ford (b) (4) (b) (4)	17 Aug 2020 16:05:09
User opened query 'Per the participant response, medication was taken to prevent 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	03 Aug 2020 22:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:16:55', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92b26b3d-c534-4d14-a1cf-85a0edd7c874'	System	03 Aug 2020 22:17:06
User entered '1'	System	03 Aug 2020 22:17:06

FDA-CBER-2022-1614-6154565

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:17:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92b26b3d-c534-4d14-a1cf-85a0edd7c874'	System	03 Aug 2020 22:17:06
User entered '03 Aug 2020 18:17'	System	03 Aug 2020 22:17:06

FDA-CBER-2022-1614-6154566

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '03 Aug 2020 18:04'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154567

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '03 Aug 2020 20:34'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154568

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154569

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:36:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b4167d8c-ae99-4536-b883-68203d0694b6'	System	04 Aug 2020 01:36:58
User entered 'Yes (Y)'	System	04 Aug 2020 01:36:58

FDA-CBER-2022-1614-6154570

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:36:38', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b4167d8c-ae99-4536-b883-68203d0694b6'	System	04 Aug 2020 01:36:58
User entered '98.2'	System	04 Aug 2020 01:36:58

FDA-CBER-2022-1614-6154571

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:36:46', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b4167d8c-ae99-4536-b883-68203d0694b6'	System	04 Aug 2020 01:36:58
User entered 'Yes (Y)'	System	04 Aug 2020 01:36:58

FDA-CBER-2022-1614-6154572

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:36:50', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b4167d8c-ae99-4536-b883-68203d0694b6'	System	04 Aug 2020 01:36:58
User entered '0'	System	04 Aug 2020 01:36:58

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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)	18 Aug 2020 13:56:31
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Amy Ford (b) (4) (b) (4)	17 Aug 2020 16:05:17
User opened query 'Per the participant response, medication was taken to prevent 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	04 Aug 2020 01:36:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:36:50', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b4167d8c-ae99-4536-b883-68203d0694b6'	System	04 Aug 2020 01:36:58
User entered '1'	System	04 Aug 2020 01:36:58

FDA-CBER-2022-1614-6154574

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:36:56', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b4167d8c-ae99-4536-b883-68203d0694b6'	System	04 Aug 2020 01:36:58
User entered '03 Aug 2020 21:36'	System	04 Aug 2020 01:36:58

FDA-CBER-2022-1614-6154575

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '03 Aug 2020 21:29'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154576

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154577

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 2'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154578

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:13', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '9e770ae2-47b7-4bc6-96cd-4d769f746148'	System	04 Aug 2020 16:03:31
User entered 'Yes (Y)'	System	04 Aug 2020 16:03:31

FDA-CBER-2022-1614-6154579

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:17', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '9e770ae2-47b7-4bc6-96cd-4d769f746148'	System	04 Aug 2020 16:03:31
User entered '98.6'	System	04 Aug 2020 16:03:31

FDA-CBER-2022-1614-6154580

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:22', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '9e770ae2-47b7-4bc6-96cd-4d769f746148'	System	04 Aug 2020 16:03:31
User entered 'Yes (Y)'	System	04 Aug 2020 16:03:31

FDA-CBER-2022-1614-6154581

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:11:02
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:25', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '9e770ae2-47b7-4bc6-96cd-4d769f746148'	System	04 Aug 2020 16:03:31
User entered '0'	System	04 Aug 2020 16:03:31

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:11:02
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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)	18 Aug 2020 13:56:45
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Amy Ford (b) (4) (b) (4)	17 Aug 2020 16:05:26
User opened query 'Per the participant response, medication was taken to prevent 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	04 Aug 2020 16:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:25', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '9e770ae2-47b7-4bc6-96cd-4d769f746148'	System	04 Aug 2020 16:03:31
User entered '1'	System	04 Aug 2020 16:03:31

FDA-CBER-2022-1614-6154583

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:29', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '9e770ae2-47b7-4bc6-96cd-4d769f746148'	System	04 Aug 2020 16:03:31
User entered '04 Aug 2020 12:03'	System	04 Aug 2020 16:03:31

FDA-CBER-2022-1614-6154584

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154585

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154586

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 3'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154587

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:18', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8f830f44-51bc-4509-a8f6-2b81f64770f6'	System	05 Aug 2020 16:07:34
User entered 'Yes (Y)'	System	05 Aug 2020 16:07:34

FDA-CBER-2022-1614-6154588

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:21', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8f830f44-51bc-4509-a8f6-2b81f64770f6'	System	05 Aug 2020 16:07:34
User entered '98.2'	System	05 Aug 2020 16:07:34

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:25', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8f830f44-51bc-4509-a8f6-2b81f64770f6'	System	05 Aug 2020 16:07:34
User entered 'Yes (Y)'	System	05 Aug 2020 16:07:34

FDA-CBER-2022-1614-6154590

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:11:02
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8f830f44-51bc-4509-a8f6-2b81f64770f6'	System	05 Aug 2020 16:07:34
User entered '0'	System	05 Aug 2020 16:07:34

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:11:02
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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)	18 Aug 2020 13:57:02
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Amy Ford (b) (4) (b) (4)	17 Aug 2020 16:05:35
User opened query 'Per the participant response, medication was taken to prevent 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	05 Aug 2020 16:07:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8f830f44-51bc-4509-a8f6-2b81f64770f6'	System	05 Aug 2020 16:07:34
User entered '1'	System	05 Aug 2020 16:07:34

FDA-CBER-2022-1614-6154592

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:30', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8f830f44-51bc-4509-a8f6-2b81f64770f6'	System	05 Aug 2020 16:07:34
User entered '05 Aug 2020 12:07'	System	05 Aug 2020 16:07:34

FDA-CBER-2022-1614-6154593

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154594

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154595

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 4'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154596

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5b8b643f-9b2a-4191-9397-031d62d5a295'	System	06 Aug 2020 16:03:17
User entered 'Yes (Y)'	System	06 Aug 2020 16:03:17

FDA-CBER-2022-1614-6154597

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:04', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5b8b643f-9b2a-4191-9397-031d62d5a295'	System	06 Aug 2020 16:03:17
User entered '98.3'	System	06 Aug 2020 16:03:17

FDA-CBER-2022-1614-6154598

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:08', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5b8b643f-9b2a-4191-9397-031d62d5a295'	System	06 Aug 2020 16:03:17
User entered 'Yes (Y)'	System	06 Aug 2020 16:03:17

FDA-CBER-2022-1614-6154599

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:11:02
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5b8b643f-9b2a-4191-9397-031d62d5a295'	System	06 Aug 2020 16:03:17
User entered '0'	System	06 Aug 2020 16:03:17

FDA-CBER-2022-1614-6154600

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:11:02
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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)	18 Aug 2020 13:57:13
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Amy Ford (b) (4) (b) (4)	17 Aug 2020 16:05:45
User opened query 'Per the participant response, medication was taken to prevent 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	06 Aug 2020 16:03:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5b8b643f-9b2a-4191-9397-031d62d5a295'	System	06 Aug 2020 16:03:17
User entered '1'	System	06 Aug 2020 16:03:17

FDA-CBER-2022-1614-6154601

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:12', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5b8b643f-9b2a-4191-9397-031d62d5a295'	System	06 Aug 2020 16:03:17
User entered '06 Aug 2020 12:03'	System	06 Aug 2020 16:03:17

FDA-CBER-2022-1614-6154602

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154603

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154604

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 5'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154605

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:14:45', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8cff255c-b239-4a31-971b-2e74944539e8'	System	07 Aug 2020 16:14:58
User entered 'Yes (Y)'	System	07 Aug 2020 16:14:58

FDA-CBER-2022-1614-6154606

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:14:48', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8cff255c-b239-4a31-971b-2e74944539e8'	System	07 Aug 2020 16:14:58
User entered '98.2'	System	07 Aug 2020 16:14:58

FDA-CBER-2022-1614-6154607

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:14:51', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8cff255c-b239-4a31-971b-2e74944539e8'	System	07 Aug 2020 16:14:58
User entered 'Yes (Y)'	System	07 Aug 2020 16:14:58

FDA-CBER-2022-1614-6154608

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:11:02
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:14:53', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8cff255c-b239-4a31-971b-2e74944539e8'	System	07 Aug 2020 16:14:58
User entered '0'	System	07 Aug 2020 16:14:58

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:11:02
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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)	18 Aug 2020 13:57:24
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Amy Ford (b) (4) (b) (4)	17 Aug 2020 16:05:56
User opened query 'Per the participant response, medication was taken to prevent 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	07 Aug 2020 16:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:14:53', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8cff255c-b239-4a31-971b-2e74944539e8'	System	07 Aug 2020 16:14:58
User entered '1'	System	07 Aug 2020 16:14:58

FDA-CBER-2022-1614-6154610

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:14:56', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8cff255c-b239-4a31-971b-2e74944539e8'	System	07 Aug 2020 16:14:58
User entered '07 Aug 2020 12:14'	System	07 Aug 2020 16:14:58

FDA-CBER-2022-1614-6154611

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154612

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154613

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 6'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154614

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:21', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '75f582e2-2e40-41bc-a615-7bdac1b365d4'	System	08 Aug 2020 16:42:37
User entered 'Yes (Y)'	System	08 Aug 2020 16:42:37

FDA-CBER-2022-1614-6154615

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:25', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '75f582e2-2e40-41bc-a615-7bdac1b365d4'	System	08 Aug 2020 16:42:37
User entered '97.5'	System	08 Aug 2020 16:42:37

FDA-CBER-2022-1614-6154616

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:30', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '75f582e2-2e40-41bc-a615-7bdac1b365d4'	System	08 Aug 2020 16:42:37
User entered 'Yes (Y)'	System	08 Aug 2020 16:42:37

FDA-CBER-2022-1614-6154617

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:11:02
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '75f582e2-2e40-41bc-a615-7bdac1b365d4'	System	08 Aug 2020 16:42:37
User entered '0'	System	08 Aug 2020 16:42:37

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:11:02
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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)	18 Aug 2020 13:57:50
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Amy Ford (b) (4) (b) (4)	17 Aug 2020 16:06:07
User opened query 'Per the participant response, medication was taken to prevent 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	08 Aug 2020 16:42:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '75f582e2-2e40-41bc-a615-7bdac1b365d4'	System	08 Aug 2020 16:42:37
User entered '1'	System	08 Aug 2020 16:42:37

FDA-CBER-2022-1614-6154619

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:35', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '75f582e2-2e40-41bc-a615-7bdac1b365d4'	System	08 Aug 2020 16:42:37
User entered '08 Aug 2020 12:42'	System	08 Aug 2020 16:42:37

FDA-CBER-2022-1614-6154620

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154621

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154622

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 7'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154623

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:02:26', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c3dba537-58df-4c19-a406-f374c63d3f8b'	System	09 Aug 2020 16:02:41
User entered 'Yes (Y)'	System	09 Aug 2020 16:02:41

FDA-CBER-2022-1614-6154624

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:02:30', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c3dba537-58df-4c19-a406-f374c63d3f8b'	System	09 Aug 2020 16:02:41
User entered '97.7'	System	09 Aug 2020 16:02:41

FDA-CBER-2022-1614-6154625

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:02:33', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c3dba537-58df-4c19-a406-f374c63d3f8b'	System	09 Aug 2020 16:02:41
User entered 'Yes (Y)'	System	09 Aug 2020 16:02:41

FDA-CBER-2022-1614-6154626

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:11:02
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:02:35', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c3dba537-58df-4c19-a406-f374c63d3f8b'	System	09 Aug 2020 16:02:41
User entered '0'	System	09 Aug 2020 16:02:41

FDA-CBER-2022-1614-6154627

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:11:02
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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)	18 Aug 2020 13:58:05
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Amy Ford (b) (4) (b) (4)	17 Aug 2020 16:06:16
User opened query 'Per the participant response, medication was taken to prevent 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	09 Aug 2020 16:02:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:02:35', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c3dba537-58df-4c19-a406-f374c63d3f8b'	System	09 Aug 2020 16:02:41
User entered '1'	System	09 Aug 2020 16:02:41

FDA-CBER-2022-1614-6154628

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:02:37', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c3dba537-58df-4c19-a406-f374c63d3f8b'	System	09 Aug 2020 16:02:41
User entered '09 Aug 2020 12:02'	System	09 Aug 2020 16:02:41

FDA-CBER-2022-1614-6154629

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154630

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154631

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 16:42:37
User entered 'Day 8'	System	08 Aug 2020 16:42:37

FDA-CBER-2022-1614-6154632

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-10T12:13:52', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '38ea95c0-d1b4-41f6-bfa5-da8327303d53'	System	10 Aug 2020 16:14:07
User entered 'Yes (Y)'	System	10 Aug 2020 16:14:07

FDA-CBER-2022-1614-6154633

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-10T12:13:56', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '38ea95c0-d1b4-41f6-bfa5-da8327303d53'	System	10 Aug 2020 16:14:07
User entered '97.9'	System	10 Aug 2020 16:14:07

FDA-CBER-2022-1614-6154634

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-10T12:13:59', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '38ea95c0-d1b4-41f6-bfa5-da8327303d53'	System	10 Aug 2020 16:14:07
User entered 'Yes (Y)'	System	10 Aug 2020 16:14:07

FDA-CBER-2022-1614-6154635

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 26 Nov 2020 11:11:02
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-10T12:14:02', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '38ea95c0-d1b4-41f6-bfa5-da8327303d53'	System	10 Aug 2020 16:14:07
User entered '0'	System	10 Aug 2020 16:14:07

FDA-CBER-2022-1614-6154636

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 26 Nov 2020 11:11:02
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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)	18 Aug 2020 13:58:25
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Amy Ford (b) (4) (b) (4)	17 Aug 2020 16:06:27
User opened query 'Per the participant response, medication was taken to prevent 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	10 Aug 2020 16:14:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-10T12:14:02', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '38ea95c0-d1b4-41f6-bfa5-da8327303d53'	System	10 Aug 2020 16:14:07
User entered '1'	System	10 Aug 2020 16:14:07

FDA-CBER-2022-1614-6154637

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-10T12:14:04', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '38ea95c0-d1b4-41f6-bfa5-da8327303d53'	System	10 Aug 2020 16:14:07
User entered '10 Aug 2020 12:14'	System	10 Aug 2020 16:14:07

FDA-CBER-2022-1614-6154638

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 16:42:37

FDA-CBER-2022-1614-6154639

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 16:42:37

FDA-CBER-2022-1614-6154640

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(9)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Query 'Per CDM: Timepoint Day 9 is not completed. Please update applicable fields as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 10:09:38
User opened query 'Per CDM: Timepoint Day 9 is not completed. Please update applicable fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Aug 2020 14:01:05
Data entry locked.	System	09 Aug 2020 16:02:41
User entered 'Day 9'	System	09 Aug 2020 16:02:41

FDA-CBER-2022-1614-6154641

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(9)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 16:02:41

FDA-CBER-2022-1614-6154642

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(9)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 16:02:41

FDA-CBER-2022-1614-6154643

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 16:14:07
User entered 'Day 10'	System	10 Aug 2020 16:14:07

FDA-CBER-2022-1614-6154644

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-12T13:01:20', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '3f881402-fca9-4df5-a588-fb81a05b7b21'	System	12 Aug 2020 17:01:51
User entered 'Yes (Y)'	System	12 Aug 2020 17:01:51

FDA-CBER-2022-1614-6154645

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-12T13:01:26', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '3f881402-fca9-4df5-a588-fb81a05b7b21'	System	12 Aug 2020 17:01:51
User entered '98.5'	System	12 Aug 2020 17:01:51

FDA-CBER-2022-1614-6154646

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-12T13:01:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '3f881402-fca9-4df5-a588-fb81a05b7b21'	System	12 Aug 2020 17:01:51
User entered 'Yes (Y)'	System	12 Aug 2020 17:01:51

FDA-CBER-2022-1614-6154647

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 26 Nov 2020 11:11:02
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-12T13:01:34', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '3f881402-fca9-4df5-a588-fb81a05b7b21'	System	12 Aug 2020 17:01:51
User entered '0'	System	12 Aug 2020 17:01:51

FDA-CBER-2022-1614-6154648

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 26 Nov 2020 11:11:02
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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)	29 Sep 2020 06:38:49
Query 'Per the participant response, medication was taken to prevent 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 'subject contacted' (Site from System).	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:19:31
User opened query 'Per the participant response, medication was taken to prevent 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	12 Aug 2020 17:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-12T13:01:34', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '3f881402-fca9-4df5-a588-fb81a05b7b21'	System	12 Aug 2020 17:01:51
User entered '1'	System	12 Aug 2020 17:01:51

FDA-CBER-2022-1614-6154649

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-12T13:01:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '3f881402-fca9-4df5-a588-fb81a05b7b21'	System	12 Aug 2020 17:01:51
User entered '12 Aug 2020 13:01'	System	12 Aug 2020 17:01:51

FDA-CBER-2022-1614-6154650

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 16:14:07

FDA-CBER-2022-1614-6154651

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 16:14:07

FDA-CBER-2022-1614-6154652

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:01:51
User entered 'Day 11'	System	12 Aug 2020 17:01:51

FDA-CBER-2022-1614-6154653

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-13T12:32:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'fedd1a6e-7783-4059-8930-842e9f40fcce'	System	13 Aug 2020 16:32:22
User entered 'Yes (Y)'	System	13 Aug 2020 16:32:22

FDA-CBER-2022-1614-6154654

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-13T12:32:13', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'fedd1a6e-7783-4059-8930-842e9f40fcce'	System	13 Aug 2020 16:32:22
User entered '98.3'	System	13 Aug 2020 16:32:22

FDA-CBER-2022-1614-6154655

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-13T12:32:16', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'fedd1a6e-7783-4059-8930-842e9f40fcce'	System	13 Aug 2020 16:32:22
User entered 'Yes (Y)'	System	13 Aug 2020 16:32:22

FDA-CBER-2022-1614-6154656

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 26 Nov 2020 11:11:02
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-13T12:32:18', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'fedd1a6e-7783-4059-8930-842e9f40fcce'	System	13 Aug 2020 16:32:22
User entered '0'	System	13 Aug 2020 16:32:22

FDA-CBER-2022-1614-6154657

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 26 Nov 2020 11:11:02
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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)	28 Sep 2020 12:11:38
Query 'Per the participant response, medication was taken to prevent 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 'subject contacted' (Site from System).	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:19:38
User opened query 'Per the participant response, medication was taken to prevent 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	13 Aug 2020 16:32:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-13T12:32:18', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'fedd1a6e-7783-4059-8930-842e9f40fcce'	System	13 Aug 2020 16:32:22
User entered '1'	System	13 Aug 2020 16:32:22

FDA-CBER-2022-1614-6154658

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-13T12:32:21', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'fedd1a6e-7783-4059-8930-842e9f40fcce'	System	13 Aug 2020 16:32:22
User entered '13 Aug 2020 12:32'	System	13 Aug 2020 16:32:22

FDA-CBER-2022-1614-6154659

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:01:51

FDA-CBER-2022-1614-6154660

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:01:51

FDA-CBER-2022-1614-6154661

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:01:51
User entered 'Day 12'	System	12 Aug 2020 17:01:51

FDA-CBER-2022-1614-6154662

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-14T12:13:46', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd49650dd-79f3-4116-b79b-0f8354283246'	System	14 Aug 2020 16:14:00
User entered 'Yes (Y)'	System	14 Aug 2020 16:14:00

FDA-CBER-2022-1614-6154663

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-14T12:13:51', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd49650dd-79f3-4116-b79b-0f8354283246'	System	14 Aug 2020 16:14:00
User entered '98.0'	System	14 Aug 2020 16:14:00

FDA-CBER-2022-1614-6154664

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-14T12:13:54', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd49650dd-79f3-4116-b79b-0f8354283246'	System	14 Aug 2020 16:14:00
User entered 'Yes (Y)'	System	14 Aug 2020 16:14:00

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 26 Nov 2020 11:11:02
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-14T12:13:56', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd49650dd-79f3-4116-b79b-0f8354283246'	System	14 Aug 2020 16:14:00
User entered '0'	System	14 Aug 2020 16:14:00

FDA-CBER-2022-1614-6154666

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 26 Nov 2020 11:11:02
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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)	28 Sep 2020 13:18:48
Query 'Per the participant response, medication was taken to prevent 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 'subject contacted' (Site from System).	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:19:45
User opened query 'Per the participant response, medication was taken to prevent 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	14 Aug 2020 16:14:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-14T12:13:56', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd49650dd-79f3-4116-b79b-0f8354283246'	System	14 Aug 2020 16:14:00
User entered '1'	System	14 Aug 2020 16:14:00

FDA-CBER-2022-1614-6154667

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-14T12:13:58', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd49650dd-79f3-4116-b79b-0f8354283246'	System	14 Aug 2020 16:14:00
User entered '14 Aug 2020 12:13'	System	14 Aug 2020 16:14:00

FDA-CBER-2022-1614-6154668

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:01:51

FDA-CBER-2022-1614-6154669

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:01:51

FDA-CBER-2022-1614-6154670

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 16:32:22
User entered 'Day 13'	System	13 Aug 2020 16:32:22

FDA-CBER-2022-1614-6154671

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-15T12:05:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c22b8aac-7b95-41c6-936d-a09bedcb48ac'	System	15 Aug 2020 16:05:16
User entered 'Yes (Y)'	System	15 Aug 2020 16:05:16

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-15T12:05:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c22b8aac-7b95-41c6-936d-a09bedcb48ac'	System	15 Aug 2020 16:05:16
User entered '98.3'	System	15 Aug 2020 16:05:16

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-15T12:05:08', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c22b8aac-7b95-41c6-936d-a09bedcb48ac'	System	15 Aug 2020 16:05:16
User entered 'Yes (Y)'	System	15 Aug 2020 16:05:16

FDA-CBER-2022-1614-6154674

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 26 Nov 2020 11:11:02
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-15T12:05:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c22b8aac-7b95-41c6-936d-a09bedcb48ac'	System	15 Aug 2020 16:05:16
User entered '0'	System	15 Aug 2020 16:05:16

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 26 Nov 2020 11:11:02
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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)	28 Sep 2020 13:19:09
Query 'Per the participant response, medication was taken to prevent 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 'subject contacted' (Site from System).	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:19:52
User opened query 'Per the participant response, medication was taken to prevent 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	15 Aug 2020 16:05:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-15T12:05:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c22b8aac-7b95-41c6-936d-a09bedcb48ac'	System	15 Aug 2020 16:05:16
User entered '1'	System	15 Aug 2020 16:05:16

FDA-CBER-2022-1614-6154676

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-15T12:05:12', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c22b8aac-7b95-41c6-936d-a09bedcb48ac'	System	15 Aug 2020 16:05:16
User entered '15 Aug 2020 12:05'	System	15 Aug 2020 16:05:16

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 16:32:22

FDA-CBER-2022-1614-6154678

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 16:32:22

FDA-CBER-2022-1614-6154679

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:14:00
User entered 'Day 14'	System	14 Aug 2020 16:14:00

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-16T12:04:34', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '18ea5194-3ecc-4a06-8d5c-4cece752733d'	System	16 Aug 2020 16:05:23
User entered 'Yes (Y)'	System	16 Aug 2020 16:05:23

FDA-CBER-2022-1614-6154681

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-16T12:04:48', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '18ea5194-3ecc-4a06-8d5c-4cece752733d'	System	16 Aug 2020 16:05:23
User entered '96.8'	System	16 Aug 2020 16:05:23

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-16T12:04:55', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '18ea5194-3ecc-4a06-8d5c-4cece752733d'	System	16 Aug 2020 16:05:23
User entered 'Yes (Y)'	System	16 Aug 2020 16:05:23

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 26 Nov 2020 11:11:02
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-16T12:05:06', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '18ea5194-3ecc-4a06-8d5c-4cece752733d'	System	16 Aug 2020 16:05:23
User entered '0'	System	16 Aug 2020 16:05:23

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 26 Nov 2020 11:11:02
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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)	28 Sep 2020 13:19:33
Query 'Per the participant response, medication was taken to prevent 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 'subject contacted' (Site from System).	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:20:01
User opened query 'Per the participant response, medication was taken to prevent 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 Aug 2020 16:05:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-16T12:05:06', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '18ea5194-3ecc-4a06-8d5c-4cece752733d'	System	16 Aug 2020 16:05:23
User entered '1'	System	16 Aug 2020 16:05:23

FDA-CBER-2022-1614-6154685

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-16T12:05:19', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '18ea5194-3ecc-4a06-8d5c-4cece752733d'	System	16 Aug 2020 16:05:23
User entered '16 Aug 2020 12:05'	System	16 Aug 2020 16:05:23

FDA-CBER-2022-1614-6154686

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 16:14:00

FDA-CBER-2022-1614-6154687

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 16:14:00

FDA-CBER-2022-1614-6154688

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 16:05:16
User entered 'Day 15'	System	15 Aug 2020 16:05:16

FDA-CBER-2022-1614-6154689

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-17T12:45:51', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ab74b292-3d58-4e91-8a04-1216b1d299fd'	System	17 Aug 2020 16:46:44
User entered 'Yes (Y)'	System	17 Aug 2020 16:46:44

FDA-CBER-2022-1614-6154690

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-17T12:46:13', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ab74b292-3d58-4e91-8a04-1216b1d299fd'	System	17 Aug 2020 16:46:44
User entered '98.0'	System	17 Aug 2020 16:46:44

FDA-CBER-2022-1614-6154691

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-17T12:46:23', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ab74b292-3d58-4e91-8a04-1216b1d299fd'	System	17 Aug 2020 16:46:44
User entered 'Yes (Y)'	System	17 Aug 2020 16:46:44

FDA-CBER-2022-1614-6154692

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 26 Nov 2020 11:11:02
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-17T12:46:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ab74b292-3d58-4e91-8a04-1216b1d299fd'	System	17 Aug 2020 16:46:44
User entered '0'	System	17 Aug 2020 16:46:44

FDA-CBER-2022-1614-6154693

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 26 Nov 2020 11:11:02
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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)	28 Sep 2020 13:19:52
Query 'Per the participant response, medication was taken to prevent 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 'subject contacted' (Site from System).	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:20:10
User opened query 'Per the participant response, medication was taken to prevent 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 Aug 2020 16:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-17T12:46:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ab74b292-3d58-4e91-8a04-1216b1d299fd'	System	17 Aug 2020 16:46:44
User entered '1'	System	17 Aug 2020 16:46:44

FDA-CBER-2022-1614-6154694

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-17T12:46:38', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ab74b292-3d58-4e91-8a04-1216b1d299fd'	System	17 Aug 2020 16:46:44
User entered '17 Aug 2020 12:46'	System	17 Aug 2020 16:46:44

FDA-CBER-2022-1614-6154695

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	15 Aug 2020 16:05:16

FDA-CBER-2022-1614-6154696

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	15 Aug 2020 16:05:16

FDA-CBER-2022-1614-6154697

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 16:05:23
User entered 'Day 16'	System	16 Aug 2020 16:05:23

FDA-CBER-2022-1614-6154698

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-18T12:17:35', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0b44a613-be92-4f7e-9367-2f133eb1d3c9'	System	18 Aug 2020 17:17:47
User entered 'Yes (Y)'	System	18 Aug 2020 17:17:47

FDA-CBER-2022-1614-6154699

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-18T12:17:39', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0b44a613-be92-4f7e-9367-2f133eb1d3c9'	System	18 Aug 2020 17:17:47
User entered '98.7'	System	18 Aug 2020 17:17:47

FDA-CBER-2022-1614-6154700

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-18T12:17:42', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0b44a613-be92-4f7e-9367-2f133eb1d3c9'	System	18 Aug 2020 17:17:47
User entered 'No (N)'	System	18 Aug 2020 17:17:47

FDA-CBER-2022-1614-6154701

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-18T12:17:44', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0b44a613-be92-4f7e-9367-2f133eb1d3c9'	System	18 Aug 2020 17:17:47
User entered '18 Aug 2020 12:17'	System	18 Aug 2020 17:17:47

FDA-CBER-2022-1614-6154702

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 16:05:23

FDA-CBER-2022-1614-6154703

US3722066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 16:05:23

FDA-CBER-2022-1614-6154704

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154705

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:17:48', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'cd096edc-3d4f-430c-93d4-2a4e36a32040'	System	03 Aug 2020 22:18:29
User entered 'None (1)'	System	03 Aug 2020 22:18:29

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:18:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'cd096edc-3d4f-430c-93d4-2a4e36a32040'	System	03 Aug 2020 22:18:29
User entered 'No (N)'	System	03 Aug 2020 22:18:29

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:18:12', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'cd096edc-3d4f-430c-93d4-2a4e36a32040'	System	03 Aug 2020 22:18:29
User entered 'No (N)'	System	03 Aug 2020 22:18:29

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:18:20', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'cd096edc-3d4f-430c-93d4-2a4e36a32040'	System	03 Aug 2020 22:18:29
User entered 'None (1)'	System	03 Aug 2020 22:18:29

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:18:24', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'cd096edc-3d4f-430c-93d4-2a4e36a32040'	System	03 Aug 2020 22:18:29
User entered '03 Aug 2020 18:18'	System	03 Aug 2020 22:18:29

FDA-CBER-2022-1614-6154710

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '03 Aug 2020 18:04'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154711

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '03 Aug 2020 20:34'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154712

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154713

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:08', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bc879cd5-fbbe-48f8-b78c-67e1b1903ccc'	System	04 Aug 2020 01:37:26
User entered 'None (1)'	System	04 Aug 2020 01:37:26

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:11', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bc879cd5-fbbe-48f8-b78c-67e1b1903ccc'	System	04 Aug 2020 01:37:26
User entered 'No (N)'	System	04 Aug 2020 01:37:26

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:14', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bc879cd5-fbbe-48f8-b78c-67e1b1903ccc'	System	04 Aug 2020 01:37:26
User entered 'No (N)'	System	04 Aug 2020 01:37:26

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:20', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bc879cd5-fbbe-48f8-b78c-67e1b1903ccc'	System	04 Aug 2020 01:37:26
User entered 'None (1)'	System	04 Aug 2020 01:37:26

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:25', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bc879cd5-fbbe-48f8-b78c-67e1b1903ccc'	System	04 Aug 2020 01:37:26
User entered '03 Aug 2020 21:37'	System	04 Aug 2020 01:37:26

FDA-CBER-2022-1614-6154718

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '03 Aug 2020 21:29'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154719

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154720

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 2'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154721

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2e4b71a3-ae00-4a93-8e04-3d76d484bb80'	System	04 Aug 2020 16:03:49
User entered 'None (1)'	System	04 Aug 2020 16:03:49

FDA-CBER-2022-1614-6154722

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:11:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:38', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2e4b71a3-ae00-4a93-8e04-3d76d484bb80'	System	04 Aug 2020 16:03:49
User entered 'No (N)'	System	04 Aug 2020 16:03:49

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:11:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2e4b71a3-ae00-4a93-8e04-3d76d484bb80'	System	04 Aug 2020 16:03:49
User entered 'No (N)'	System	04 Aug 2020 16:03:49

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:44', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2e4b71a3-ae00-4a93-8e04-3d76d484bb80'	System	04 Aug 2020 16:03:49
User entered 'None (1)'	System	04 Aug 2020 16:03:49

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:48', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2e4b71a3-ae00-4a93-8e04-3d76d484bb80'	System	04 Aug 2020 16:03:49
User entered '04 Aug 2020 12:03'	System	04 Aug 2020 16:03:49

FDA-CBER-2022-1614-6154726

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154727

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154728

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 3'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154729

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bb3ba382-dc81-4201-ba63-998ab626eb53'	System	05 Aug 2020 16:07:49
User entered 'None (1)'	System	05 Aug 2020 16:07:49

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:11:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:39', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bb3ba382-dc81-4201-ba63-998ab626eb53'	System	05 Aug 2020 16:07:49
User entered 'No (N)'	System	05 Aug 2020 16:07:49

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:11:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bb3ba382-dc81-4201-ba63-998ab626eb53'	System	05 Aug 2020 16:07:49
User entered 'No (N)'	System	05 Aug 2020 16:07:49

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:44', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bb3ba382-dc81-4201-ba63-998ab626eb53'	System	05 Aug 2020 16:07:49
User entered 'None (1)'	System	05 Aug 2020 16:07:49

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:47', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bb3ba382-dc81-4201-ba63-998ab626eb53'	System	05 Aug 2020 16:07:49
User entered '05 Aug 2020 12:07'	System	05 Aug 2020 16:07:49

FDA-CBER-2022-1614-6154734

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154735

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154736

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 4'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154737

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:18', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5923cd01-df17-41ea-8143-da453cc50071'	System	06 Aug 2020 16:03:32
User entered 'None (1)'	System	06 Aug 2020 16:03:32

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:11:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:21', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5923cd01-df17-41ea-8143-da453cc50071'	System	06 Aug 2020 16:03:32
User entered 'No (N)'	System	06 Aug 2020 16:03:32

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:11:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:23', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5923cd01-df17-41ea-8143-da453cc50071'	System	06 Aug 2020 16:03:32
User entered 'No (N)'	System	06 Aug 2020 16:03:32

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:26', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5923cd01-df17-41ea-8143-da453cc50071'	System	06 Aug 2020 16:03:32
User entered 'None (1)'	System	06 Aug 2020 16:03:32

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5923cd01-df17-41ea-8143-da453cc50071'	System	06 Aug 2020 16:03:32
User entered '06 Aug 2020 12:03'	System	06 Aug 2020 16:03:32

FDA-CBER-2022-1614-6154742

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154743

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154744

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 5'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154745

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bae7238b-a978-4306-bdac-58ea4eca1554'	System	07 Aug 2020 16:15:12
User entered 'None (1)'	System	07 Aug 2020 16:15:12

FDA-CBER-2022-1614-6154746

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:11:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:03', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bae7238b-a978-4306-bdac-58ea4eca1554'	System	07 Aug 2020 16:15:12
User entered 'No (N)'	System	07 Aug 2020 16:15:12

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:11:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bae7238b-a978-4306-bdac-58ea4eca1554'	System	07 Aug 2020 16:15:12
User entered 'No (N)'	System	07 Aug 2020 16:15:12

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:07', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bae7238b-a978-4306-bdac-58ea4eca1554'	System	07 Aug 2020 16:15:12
User entered 'None (1)'	System	07 Aug 2020 16:15:12

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bae7238b-a978-4306-bdac-58ea4eca1554'	System	07 Aug 2020 16:15:12
User entered '07 Aug 2020 12:15'	System	07 Aug 2020 16:15:12

FDA-CBER-2022-1614-6154750

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154751

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154752

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 6'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154753

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:38', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c2f3c5d4-d402-4b58-aba7-e4d21b455fd6'	System	08 Aug 2020 16:42:49
User entered 'None (1)'	System	08 Aug 2020 16:42:49

FDA-CBER-2022-1614-6154754

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:11:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:40', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c2f3c5d4-d402-4b58-aba7-e4d21b455fd6'	System	08 Aug 2020 16:42:49
User entered 'No (N)'	System	08 Aug 2020 16:42:49

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:11:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:42', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c2f3c5d4-d402-4b58-aba7-e4d21b455fd6'	System	08 Aug 2020 16:42:49
User entered 'No (N)'	System	08 Aug 2020 16:42:49

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:45', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c2f3c5d4-d402-4b58-aba7-e4d21b455fd6'	System	08 Aug 2020 16:42:49
User entered 'None (1)'	System	08 Aug 2020 16:42:49

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:47', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c2f3c5d4-d402-4b58-aba7-e4d21b455fd6'	System	08 Aug 2020 16:42:49
User entered '08 Aug 2020 12:42'	System	08 Aug 2020 16:42:49

FDA-CBER-2022-1614-6154758

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154759

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154760

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 7'	System	03 Aug 2020 21:49:25

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:02:43', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd1f7c46a-1ad1-4ddb-ad51-370fbfe84e5b'	System	09 Aug 2020 16:03:03
User entered 'None (1)'	System	09 Aug 2020 16:03:03

FDA-CBER-2022-1614-6154762

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:11:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:02:50', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd1f7c46a-1ad1-4ddb-ad51-370fbfe84e5b'	System	09 Aug 2020 16:03:03
User entered 'No (N)'	System	09 Aug 2020 16:03:03

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:11:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:02:53', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd1f7c46a-1ad1-4ddb-ad51-370fbfe84e5b'	System	09 Aug 2020 16:03:03
User entered 'No (N)'	System	09 Aug 2020 16:03:03

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:02:55', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd1f7c46a-1ad1-4ddb-ad51-370fbfe84e5b'	System	09 Aug 2020 16:03:03
User entered 'None (1)'	System	09 Aug 2020 16:03:03

FDA-CBER-2022-1614-6154765

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:03:02', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd1f7c46a-1ad1-4ddb-ad51-370fbfe84e5b'	System	09 Aug 2020 16:03:03
User entered '09 Aug 2020 12:03'	System	09 Aug 2020 16:03:03

FDA-CBER-2022-1614-6154766

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154767

US3722066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154768

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154769

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:18:31', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7af66d27-476f-42c9-8113-c6af6bbe6b3b'	System	03 Aug 2020 22:19:12
User entered 'None (0)'	System	03 Aug 2020 22:19:12

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:18:37', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7af66d27-476f-42c9-8113-c6af6bbe6b3b'	System	03 Aug 2020 22:19:12
User entered 'None (0)'	System	03 Aug 2020 22:19:12

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:18:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7af66d27-476f-42c9-8113-c6af6bbe6b3b'	System	03 Aug 2020 22:19:12
User entered 'None (0)'	System	03 Aug 2020 22:19:12

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:18:46', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7af66d27-476f-42c9-8113-c6af6bbe6b3b'	System	03 Aug 2020 22:19:12
User entered 'None (0)'	System	03 Aug 2020 22:19:12

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:18:49', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7af66d27-476f-42c9-8113-c6af6bbe6b3b'	System	03 Aug 2020 22:19:12
User entered 'None (0)'	System	03 Aug 2020 22:19:12

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:18:52', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7af66d27-476f-42c9-8113-c6af6bbe6b3b'	System	03 Aug 2020 22:19:12
User entered 'None (0)'	System	03 Aug 2020 22:19:12

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:19:06', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7af66d27-476f-42c9-8113-c6af6bbe6b3b'	System	03 Aug 2020 22:19:12
User entered 'No (N)'	System	03 Aug 2020 22:19:12

FDA-CBER-2022-1614-6154776

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:19:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7af66d27-476f-42c9-8113-c6af6bbe6b3b'	System	03 Aug 2020 22:19:12
User entered '03 Aug 2020 18:19'	System	03 Aug 2020 22:19:12

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '03 Aug 2020 18:04'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154778

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '03 Aug 2020 20:34'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154779

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154780

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:33', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '13652d0b-62ad-483d-9e2b-b9501bc0899e'	System	04 Aug 2020 01:38:01
User entered 'None (0)'	System	04 Aug 2020 01:38:01

FDA-CBER-2022-1614-6154781

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:35', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '13652d0b-62ad-483d-9e2b-b9501bc0899e'	System	04 Aug 2020 01:38:01
User entered 'None (0)'	System	04 Aug 2020 01:38:01

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:38', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '13652d0b-62ad-483d-9e2b-b9501bc0899e'	System	04 Aug 2020 01:38:01
User entered 'None (0)'	System	04 Aug 2020 01:38:01

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:40', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '13652d0b-62ad-483d-9e2b-b9501bc0899e'	System	04 Aug 2020 01:38:01
User entered 'None (0)'	System	04 Aug 2020 01:38:01

FDA-CBER-2022-1614-6154784

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:43', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '13652d0b-62ad-483d-9e2b-b9501bc0899e'	System	04 Aug 2020 01:38:01
User entered 'None (0)'	System	04 Aug 2020 01:38:01

FDA-CBER-2022-1614-6154785

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:46', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '13652d0b-62ad-483d-9e2b-b9501bc0899e'	System	04 Aug 2020 01:38:01
User entered 'None (0)'	System	04 Aug 2020 01:38:01

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:56', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '13652d0b-62ad-483d-9e2b-b9501bc0899e'	System	04 Aug 2020 01:38:01
User entered 'No (N)'	System	04 Aug 2020 01:38:01

FDA-CBER-2022-1614-6154787

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:59', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '13652d0b-62ad-483d-9e2b-b9501bc0899e'	System	04 Aug 2020 01:38:01
User entered '03 Aug 2020 21:37'	System	04 Aug 2020 01:38:01

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '03 Aug 2020 21:29'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154789

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154790

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 2'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154791

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:52', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '09b330d3-2489-4aa3-b452-527fd0b38a77'	System	04 Aug 2020 16:04:15
User entered 'None (0)'	System	04 Aug 2020 16:04:15

FDA-CBER-2022-1614-6154792

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:55', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '09b330d3-2489-4aa3-b452-527fd0b38a77'	System	04 Aug 2020 16:04:15
User entered 'None (0)'	System	04 Aug 2020 16:04:15

FDA-CBER-2022-1614-6154793

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:57', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '09b330d3-2489-4aa3-b452-527fd0b38a77'	System	04 Aug 2020 16:04:15
User entered 'None (0)'	System	04 Aug 2020 16:04:15

FDA-CBER-2022-1614-6154794

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:59', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '09b330d3-2489-4aa3-b452-527fd0b38a77'	System	04 Aug 2020 16:04:15
User entered 'None (0)'	System	04 Aug 2020 16:04:15

FDA-CBER-2022-1614-6154795

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:04:02', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '09b330d3-2489-4aa3-b452-527fd0b38a77'	System	04 Aug 2020 16:04:15
User entered 'None (0)'	System	04 Aug 2020 16:04:15

FDA-CBER-2022-1614-6154796

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:04:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '09b330d3-2489-4aa3-b452-527fd0b38a77'	System	04 Aug 2020 16:04:15
User entered 'None (0)'	System	04 Aug 2020 16:04:15

FDA-CBER-2022-1614-6154797

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:04:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '09b330d3-2489-4aa3-b452-527fd0b38a77'	System	04 Aug 2020 16:04:15
User entered 'No (N)'	System	04 Aug 2020 16:04:15

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:04:12', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '09b330d3-2489-4aa3-b452-527fd0b38a77'	System	04 Aug 2020 16:04:15
User entered '04 Aug 2020 12:04'	System	04 Aug 2020 16:04:15

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154800

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154801

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 3'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154802

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:51', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2158af88-0a90-43d9-be41-74b08c03652f'	System	05 Aug 2020 16:08:12
User entered 'None (0)'	System	05 Aug 2020 16:08:12

FDA-CBER-2022-1614-6154803

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:53', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2158af88-0a90-43d9-be41-74b08c03652f'	System	05 Aug 2020 16:08:12
User entered 'None (0)'	System	05 Aug 2020 16:08:12

FDA-CBER-2022-1614-6154804

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:55', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2158af88-0a90-43d9-be41-74b08c03652f'	System	05 Aug 2020 16:08:12
User entered 'None (0)'	System	05 Aug 2020 16:08:12

FDA-CBER-2022-1614-6154805

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:58', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2158af88-0a90-43d9-be41-74b08c03652f'	System	05 Aug 2020 16:08:12
User entered 'None (0)'	System	05 Aug 2020 16:08:12

FDA-CBER-2022-1614-6154806

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:08:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2158af88-0a90-43d9-be41-74b08c03652f'	System	05 Aug 2020 16:08:12
User entered 'None (0)'	System	05 Aug 2020 16:08:12

FDA-CBER-2022-1614-6154807

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:08:02', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2158af88-0a90-43d9-be41-74b08c03652f'	System	05 Aug 2020 16:08:12
User entered 'None (0)'	System	05 Aug 2020 16:08:12

FDA-CBER-2022-1614-6154808

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:08:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2158af88-0a90-43d9-be41-74b08c03652f'	System	05 Aug 2020 16:08:12
User entered 'No (N)'	System	05 Aug 2020 16:08:12

FDA-CBER-2022-1614-6154809

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:08:07', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2158af88-0a90-43d9-be41-74b08c03652f'	System	05 Aug 2020 16:08:12
User entered '05 Aug 2020 12:08'	System	05 Aug 2020 16:08:12

FDA-CBER-2022-1614-6154810

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154811

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154812

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 4'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154813

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:34', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '62559a7c-917c-4917-b3e3-fcab1e17477d'	System	06 Aug 2020 16:03:52
User entered 'None (0)'	System	06 Aug 2020 16:03:52

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '62559a7c-917c-4917-b3e3-fcab1e17477d'	System	06 Aug 2020 16:03:52
User entered 'None (0)'	System	06 Aug 2020 16:03:52

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:39', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '62559a7c-917c-4917-b3e3-fcab1e17477d'	System	06 Aug 2020 16:03:52
User entered 'None (0)'	System	06 Aug 2020 16:03:52

FDA-CBER-2022-1614-6154816

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '62559a7c-917c-4917-b3e3-fcab1e17477d'	System	06 Aug 2020 16:03:52
User entered 'None (0)'	System	06 Aug 2020 16:03:52

FDA-CBER-2022-1614-6154817

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:43', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '62559a7c-917c-4917-b3e3-fcab1e17477d'	System	06 Aug 2020 16:03:52
User entered 'None (0)'	System	06 Aug 2020 16:03:52

FDA-CBER-2022-1614-6154818

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:45', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '62559a7c-917c-4917-b3e3-fcab1e17477d'	System	06 Aug 2020 16:03:52
User entered 'None (0)'	System	06 Aug 2020 16:03:52

FDA-CBER-2022-1614-6154819

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:48', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '62559a7c-917c-4917-b3e3-fcab1e17477d'	System	06 Aug 2020 16:03:52
User entered 'No (N)'	System	06 Aug 2020 16:03:52

FDA-CBER-2022-1614-6154820

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:50', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '62559a7c-917c-4917-b3e3-fcab1e17477d'	System	06 Aug 2020 16:03:52
User entered '06 Aug 2020 12:03'	System	06 Aug 2020 16:03:52

FDA-CBER-2022-1614-6154821

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154822

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154823

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 5'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154824

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:15', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92683bf3-e68d-4079-b67a-090e1a1e56ef'	System	07 Aug 2020 16:15:34
User entered 'None (0)'	System	07 Aug 2020 16:15:34

FDA-CBER-2022-1614-6154825

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:17', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92683bf3-e68d-4079-b67a-090e1a1e56ef'	System	07 Aug 2020 16:15:34
User entered 'None (0)'	System	07 Aug 2020 16:15:34

FDA-CBER-2022-1614-6154826

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:19', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92683bf3-e68d-4079-b67a-090e1a1e56ef'	System	07 Aug 2020 16:15:34
User entered 'None (0)'	System	07 Aug 2020 16:15:34

FDA-CBER-2022-1614-6154827

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:21', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92683bf3-e68d-4079-b67a-090e1a1e56ef'	System	07 Aug 2020 16:15:34
User entered 'None (0)'	System	07 Aug 2020 16:15:34

FDA-CBER-2022-1614-6154828

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:23', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92683bf3-e68d-4079-b67a-090e1a1e56ef'	System	07 Aug 2020 16:15:34
User entered 'None (0)'	System	07 Aug 2020 16:15:34

FDA-CBER-2022-1614-6154829

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:24', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92683bf3-e68d-4079-b67a-090e1a1e56ef'	System	07 Aug 2020 16:15:34
User entered 'None (0)'	System	07 Aug 2020 16:15:34

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:27', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92683bf3-e68d-4079-b67a-090e1a1e56ef'	System	07 Aug 2020 16:15:34
User entered 'No (N)'	System	07 Aug 2020 16:15:34

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:29', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92683bf3-e68d-4079-b67a-090e1a1e56ef'	System	07 Aug 2020 16:15:34
User entered '07 Aug 2020 12:15'	System	07 Aug 2020 16:15:34

FDA-CBER-2022-1614-6154832

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154833

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 6'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154835

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:51', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a202ca-c543-4b69-a4cc-b1c6a4ea4546'	System	08 Aug 2020 16:43:08
User entered 'None (0)'	System	08 Aug 2020 16:43:08

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:53', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a202ca-c543-4b69-a4cc-b1c6a4ea4546'	System	08 Aug 2020 16:43:08
User entered 'None (0)'	System	08 Aug 2020 16:43:08

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:54', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a202ca-c543-4b69-a4cc-b1c6a4ea4546'	System	08 Aug 2020 16:43:08
User entered 'None (0)'	System	08 Aug 2020 16:43:08

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:56', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a202ca-c543-4b69-a4cc-b1c6a4ea4546'	System	08 Aug 2020 16:43:08
User entered 'None (0)'	System	08 Aug 2020 16:43:08

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:58', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a202ca-c543-4b69-a4cc-b1c6a4ea4546'	System	08 Aug 2020 16:43:08
User entered 'None (0)'	System	08 Aug 2020 16:43:08

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:43:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a202ca-c543-4b69-a4cc-b1c6a4ea4546'	System	08 Aug 2020 16:43:08
User entered 'None (0)'	System	08 Aug 2020 16:43:08

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:43:03', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a202ca-c543-4b69-a4cc-b1c6a4ea4546'	System	08 Aug 2020 16:43:08
User entered 'No (N)'	System	08 Aug 2020 16:43:08

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:43:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a202ca-c543-4b69-a4cc-b1c6a4ea4546'	System	08 Aug 2020 16:43:08
User entered '08 Aug 2020 12:43'	System	08 Aug 2020 16:43:08

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154845

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 7'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154846

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:03:06', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '23f35d81-ee52-40ea-8bdd-814e108d4d21'	System	09 Aug 2020 16:03:24
User entered 'None (0)'	System	09 Aug 2020 16:03:24

FDA-CBER-2022-1614-6154847

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:03:08', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '23f35d81-ee52-40ea-8bdd-814e108d4d21'	System	09 Aug 2020 16:03:24
User entered 'None (0)'	System	09 Aug 2020 16:03:24

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:03:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '23f35d81-ee52-40ea-8bdd-814e108d4d21'	System	09 Aug 2020 16:03:24
User entered 'None (0)'	System	09 Aug 2020 16:03:24

FDA-CBER-2022-1614-6154849

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:03:11', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '23f35d81-ee52-40ea-8bdd-814e108d4d21'	System	09 Aug 2020 16:03:24
User entered 'None (0)'	System	09 Aug 2020 16:03:24

FDA-CBER-2022-1614-6154850

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:03:13', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '23f35d81-ee52-40ea-8bdd-814e108d4d21'	System	09 Aug 2020 16:03:24
User entered 'None (0)'	System	09 Aug 2020 16:03:24

FDA-CBER-2022-1614-6154851

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:03:15', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '23f35d81-ee52-40ea-8bdd-814e108d4d21'	System	09 Aug 2020 16:03:24
User entered 'None (0)'	System	09 Aug 2020 16:03:24

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:03:18', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '23f35d81-ee52-40ea-8bdd-814e108d4d21'	System	09 Aug 2020 16:03:24
User entered 'No (N)'	System	09 Aug 2020 16:03:24

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:03:20', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '23f35d81-ee52-40ea-8bdd-814e108d4d21'	System	09 Aug 2020 16:03:24
User entered '09 Aug 2020 12:03'	System	09 Aug 2020 16:03:24

FDA-CBER-2022-1614-6154854

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154855

US3722066
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6154856

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 16:42:37
User entered 'Day 8'	System	08 Aug 2020 16:42:37

FDA-CBER-2022-1614-6154857

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-10T12:14:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8b3f8e23-6d02-4737-bc1f-e43746fe6098'	System	10 Aug 2020 16:14:14
User entered 'No (N)'	System	10 Aug 2020 16:14:14

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-10T12:14:13', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8b3f8e23-6d02-4737-bc1f-e43746fe6098'	System	10 Aug 2020 16:14:14
User entered '10 Aug 2020 12:14'	System	10 Aug 2020 16:14:14

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 16:42:37

FDA-CBER-2022-1614-6154860

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 16:42:37

FDA-CBER-2022-1614-6154861

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Aug 2020 16:02:41
User entered 'Day 9'	System	09 Aug 2020 16:02:41

FDA-CBER-2022-1614-6154862

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 16:02:41

FDA-CBER-2022-1614-6154863

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 16:02:41

FDA-CBER-2022-1614-6154864

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 16:14:07
User entered 'Day 10'	System	10 Aug 2020 16:14:07

FDA-CBER-2022-1614-6154865

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-12T13:01:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'fc287c22-abbe-40b7-a74d-5c4fff485944'	System	12 Aug 2020 17:01:56
User entered 'No (N)'	System	12 Aug 2020 17:01:56

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-12T13:01:43', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'fc287c22-abbe-40b7-a74d-5c4fff485944'	System	12 Aug 2020 17:01:56
User entered '12 Aug 2020 13:01'	System	12 Aug 2020 17:01:56

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 16:14:07

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 16:14:07

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:01:51
User entered 'Day 11'	System	12 Aug 2020 17:01:51

FDA-CBER-2022-1614-6154870

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-13T12:32:25', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bf984dc5-91b1-4b13-ad24-61ce2ba3bc37'	System	13 Aug 2020 16:32:29
User entered 'No (N)'	System	13 Aug 2020 16:32:29

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-13T12:32:27', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bf984dc5-91b1-4b13-ad24-61ce2ba3bc37'	System	13 Aug 2020 16:32:29
User entered '13 Aug 2020 12:32'	System	13 Aug 2020 16:32:29

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:01:51

FDA-CBER-2022-1614-6154873

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:01:51

FDA-CBER-2022-1614-6154874

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(12)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:01:51
User entered 'Day 12'	System	12 Aug 2020 17:01:51

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(12)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-14T12:14:39', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5d32548d-40f8-402f-8f05-32d67f77ff41'	System	14 Aug 2020 16:14:43
User entered 'No (N)'	System	14 Aug 2020 16:14:43

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(12)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-14T12:14:40', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5d32548d-40f8-402f-8f05-32d67f77ff41'	System	14 Aug 2020 16:14:43
User entered '14 Aug 2020 12:14'	System	14 Aug 2020 16:14:43

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(12)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:01:51

FDA-CBER-2022-1614-6154878

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(12)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:01:51

FDA-CBER-2022-1614-6154879

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(13)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 16:32:22
User entered 'Day 13'	System	13 Aug 2020 16:32:22

FDA-CBER-2022-1614-6154880

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(13)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-15T12:05:16', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '43d82bda-e765-4850-9cd4-f0d42ead2b95'	System	15 Aug 2020 16:05:22
User entered 'No (N)'	System	15 Aug 2020 16:05:22

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(13)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-15T12:05:19', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '43d82bda-e765-4850-9cd4-f0d42ead2b95'	System	15 Aug 2020 16:05:22
User entered '15 Aug 2020 12:05'	System	15 Aug 2020 16:05:22

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(13)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 16:32:22

FDA-CBER-2022-1614-6154883

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(13)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 16:32:22

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(14)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:14:00
User entered 'Day 14'	System	14 Aug 2020 16:14:00

FDA-CBER-2022-1614-6154885

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(14)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-16T12:05:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '74d59fdc-2d8d-4d39-aecb-1aba5a95980a'	System	16 Aug 2020 16:05:37
User entered 'No (N)'	System	16 Aug 2020 16:05:37

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(14)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-16T12:05:33', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '74d59fdc-2d8d-4d39-aecb-1aba5a95980a'	System	16 Aug 2020 16:05:37
User entered '16 Aug 2020 12:05'	System	16 Aug 2020 16:05:37

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(14)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 16:14:00

FDA-CBER-2022-1614-6154888

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(14)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 16:14:00

FDA-CBER-2022-1614-6154889

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(15)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 16:05:16
User entered 'Day 15'	System	15 Aug 2020 16:05:16

FDA-CBER-2022-1614-6154890

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(15)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-17T12:46:47', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd99264ae-57b6-4763-a8bf-bf27a22148ae'	System	17 Aug 2020 16:46:59
User entered 'No (N)'	System	17 Aug 2020 16:46:59

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(15)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-17T12:46:52', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd99264ae-57b6-4763-a8bf-bf27a22148ae'	System	17 Aug 2020 16:46:59
User entered '17 Aug 2020 12:46'	System	17 Aug 2020 16:46:59

FDA-CBER-2022-1614-6154892

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(15)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	15 Aug 2020 16:05:16

FDA-CBER-2022-1614-6154893

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(15)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	15 Aug 2020 16:05:16

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(16)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 16:05:23
User entered 'Day 16'	System	16 Aug 2020 16:05:23

FDA-CBER-2022-1614-6154895

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(16)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-18T12:17:49', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '681b04b1-67c3-4b00-afc6-db41184c7326'	System	18 Aug 2020 17:17:54
User entered 'No (N)'	System	18 Aug 2020 17:17:54

FDA-CBER-2022-1614-6154896

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(16)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-18T12:17:51', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '681b04b1-67c3-4b00-afc6-db41184c7326'	System	18 Aug 2020 17:17:54
User entered '18 Aug 2020 12:17'	System	18 Aug 2020 17:17:54

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(16)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 16:05:23

FDA-CBER-2022-1614-6154898

US3722066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(16)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 16:05:23

US3722066
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 01:13:30

FDA-CBER-2022-1614-6154900

US3722066
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 01:13:30

FDA-CBER-2022-1614-6154901

US3722066
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 01:13:30

FDA-CBER-2022-1614-6154902

US3722066
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 01:13:30

FDA-CBER-2022-1614-6154903

US3722066
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 01:13:42

FDA-CBER-2022-1614-6154904

US3722066
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:13:42

FDA-CBER-2022-1614-6154905

US3722066
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	26 Aug 2020 01:35:15

FDA-CBER-2022-1614-6154906

US3722066
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '18 Aug 2020'	Kayla Peay (b) (4) (b) (4)	26 Aug 2020 01:35:15

FDA-CBER-2022-1614-6154907

US3722066
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4) (b) (4)	26 Aug 2020 01:35:15

FDA-CBER-2022-1614-6154908

US3722066
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	26 Aug 2020 01:35:15

FDA-CBER-2022-1614-6154909

US3722066
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	26 Aug 2020 01:35:20

FDA-CBER-2022-1614-6154910

US3722066
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 01:35:20

FDA-CBER-2022-1614-6154911

US3722066
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	27 Aug 2020 12:59:33

FDA-CBER-2022-1614-6154912

US3722066
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Kayla Peay (b) (4) (b) (4)	27 Aug 2020 12:59:33

FDA-CBER-2022-1614-6154913

US3722066
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4) (b) (4)	27 Aug 2020 12:59:33

FDA-CBER-2022-1614-6154914

US3722066
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	27 Aug 2020 12:59:33

FDA-CBER-2022-1614-6154915

US3722066
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	27 Aug 2020 12:59:25

FDA-CBER-2022-1614-6154916

US3722066
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 12:59:25

FDA-CBER-2022-1614-6154917

US3722066
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02
Was this visit performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	28 Aug 2020 16:19:29

FDA-CBER-2022-1614-6154918

US3722066
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	28 Aug 2020 19:23:44
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Per protocol subject is in window' (Site from System).	Sara Poff (b) (4) (b) (4)	28 Aug 2020 16:19:44
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	28 Aug 2020 16:19:29
User entered '28 Aug 2020'	Sara Poff (b) (4) (b) (4)	28 Aug 2020 16:19:29

FDA-CBER-2022-1614-6154919

US3722066
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Sara Poff (b) (4) (b) (4)	28 Aug 2020 16:19:29

FDA-CBER-2022-1614-6154920

US3722066
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02
Folder OID

Audit	User	Time (GMT)
User entered 'VISIT2'	System	28 Aug 2020 16:19:29

FDA-CBER-2022-1614-6154921

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154922

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154923

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154924

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '10:35'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154925

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '28 Aug 2020 10:35'	System	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154926

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User entered '98.7' F	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154927

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Route of measurement

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154928

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
If Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154929

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Pulse *(xxx)*

Audit	User	Time (GMT)
User entered '71'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154930

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154931

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User entered '19'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154932

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154933

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '144'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154934

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154935

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '83'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154936

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:11:02
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154937

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154938

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154939

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154940

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 18:04:23
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Aug 2020 18:04:23
User entered '12:21' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 18:04:23
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 15:28:30
User entered empty.	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154941

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:21'	System	28 Aug 2020 18:04:23
User entered empty.	System	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154942

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 18:04:23
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Aug 2020 18:04:23
User entered '97.5' F reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 18:04:23
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 15:28:30
User entered empty.	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154943

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Route of measurement

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154944

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
If Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154945

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Pulse *(xxx)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 18:04:23
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Aug 2020 18:04:23
User entered '76' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 18:04:23
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 15:28:30
User entered empty.	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154946

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Aug 2020 18:04:23
User entered empty.	System	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154947

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 18:04:23
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Aug 2020 18:04:23
User entered '18' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 18:04:23
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 15:28:30
User entered empty.	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154948

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Aug 2020 18:04:23
User entered empty.	System	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154949

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 18:04:23
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Aug 2020 18:04:23
User entered '129' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 18:04:23
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 15:28:30
User entered empty.	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154950

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 18:04:23
User entered empty.	System	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154951

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 18:04:23
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Aug 2020 18:04:23
User entered '89' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 18:04:23
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 15:28:30
User entered empty.	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

FDA-CBER-2022-1614-6154952

US3722066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:11:02
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 18:04:23
User entered empty.	System	28 Aug 2020 15:28:30

US3722066
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:11:02
Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:39

FDA-CBER-2022-1614-6154954

US3722066
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:11:02
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:39

FDA-CBER-2022-1614-6154955

US3722066
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:11:02
Was study treatment given?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6154956

US3722066
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:11:02
If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Sara Poff (b) (4) (b) (4)	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6154957

US3722066
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:11:02
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Sara Poff (b) (4) (b) (4)	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6154958

US3722066
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:11:02
What was the study treatment?

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6154959

US3722066
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:11:02
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Sara Poff (b) (4) (b) (4)	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6154960

US3722066
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:11:02
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '11:51'	Sara Poff (b) (4) (b) (4)	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6154961

US3722066
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:11:02
Treatment Date and Time (derived)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:51'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6154962

US3722066
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:11:02
Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Sara Poff (b) (4) (b) (4)	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6154963

US3722066
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:11:02
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6154964

US3722066
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:11:02
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6154965

US3722066
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:11:02
Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 18:03:50

FDA-CBER-2022-1614-6154966

US3722066
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:11:02
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 18:03:50

FDA-CBER-2022-1614-6154967

US3722066
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:11:02
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '11:25'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 18:03:50

FDA-CBER-2022-1614-6154968

US3722066
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:11:02
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:25'	System	28 Aug 2020 18:03:50

US3722066
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 26 Nov 2020 11:11:02
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:59

FDA-CBER-2022-1614-6154970

US3722066
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 11:11:02
Lab Test

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:59

FDA-CBER-2022-1614-6154971

US3722066
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 11:11:02
Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:59

FDA-CBER-2022-1614-6154972

US3722066
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 11:11:02
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
User entered '10:57'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:59

FDA-CBER-2022-1614-6154973

US3722066
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 11:11:02
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '28 Aug 2020 10:57'	System	28 Aug 2020 15:28:59

FDA-CBER-2022-1614-6154974

US3722066
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 11:11:02
Lab Test

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:59

FDA-CBER-2022-1614-6154975

US3722066
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 11:11:02
Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:59

FDA-CBER-2022-1614-6154976

US3722066
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 11:11:02
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
User entered '10:57'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:59

FDA-CBER-2022-1614-6154977

US3722066
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 11:11:02
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '28 Aug 2020 10:57'	System	28 Aug 2020 15:28:59

FDA-CBER-2022-1614-6154978

US3722066
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	28 Aug 2020 16:20:15

FDA-CBER-2022-1614-6154979

US3722066
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 16:20:15

FDA-CBER-2022-1614-6154980

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6154981

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:21:13', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c80e38cf-bbc4-42dc-903d-a1e99b18fd75'	System	28 Aug 2020 16:21:39
User entered 'Yes (Y)'	System	28 Aug 2020 16:21:39

FDA-CBER-2022-1614-6154982

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:21:24', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c80e38cf-bbc4-42dc-903d-a1e99b18fd75'	System	28 Aug 2020 16:21:39
User entered '97.5'	System	28 Aug 2020 16:21:39

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:21:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c80e38cf-bbc4-42dc-903d-a1e99b18fd75'	System	28 Aug 2020 16:21:39
User entered 'No (N)'	System	28 Aug 2020 16:21:39

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:21:38', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c80e38cf-bbc4-42dc-903d-a1e99b18fd75'	System	28 Aug 2020 16:21:39
User entered '28 Aug 2020 12:21'	System	28 Aug 2020 16:21:39

FDA-CBER-2022-1614-6154985

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:11'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6154986

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 14:41'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6154987

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6154988

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:50:24', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b32ec790-9b2d-433b-b3c6-1c19a757260a'	System	28 Aug 2020 19:50:37
User entered 'Yes (Y)'	System	28 Aug 2020 19:50:37

FDA-CBER-2022-1614-6154989

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:50:27', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b32ec790-9b2d-433b-b3c6-1c19a757260a'	System	28 Aug 2020 19:50:37
User entered '98.3'	System	28 Aug 2020 19:50:37

FDA-CBER-2022-1614-6154990

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:50:29', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b32ec790-9b2d-433b-b3c6-1c19a757260a'	System	28 Aug 2020 19:50:37
User entered 'No (N)'	System	28 Aug 2020 19:50:37

FDA-CBER-2022-1614-6154991

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:50:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b32ec790-9b2d-433b-b3c6-1c19a757260a'	System	28 Aug 2020 19:50:37
User entered '28 Aug 2020 15:50'	System	28 Aug 2020 19:50:37

FDA-CBER-2022-1614-6154992

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 15:36'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6154993

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6154994

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 2'	System	28 Aug 2020 16:20:07

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:11', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '1eb6e39b-0409-4d31-ba04-a1eb7c69337b'	System	30 Aug 2020 01:06:28
User entered 'Yes (Y)'	System	30 Aug 2020 01:06:28

FDA-CBER-2022-1614-6154996

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:19', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '1eb6e39b-0409-4d31-ba04-a1eb7c69337b'	System	30 Aug 2020 01:06:28
User entered '97.9'	System	30 Aug 2020 01:06:28

FDA-CBER-2022-1614-6154997

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:22', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '1eb6e39b-0409-4d31-ba04-a1eb7c69337b'	System	30 Aug 2020 01:06:28
User entered 'No (N)'	System	30 Aug 2020 01:06:28

FDA-CBER-2022-1614-6154998

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:24', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '1eb6e39b-0409-4d31-ba04-a1eb7c69337b'	System	30 Aug 2020 01:06:28
User entered '29 Aug 2020 21:06'	System	30 Aug 2020 01:06:28

FDA-CBER-2022-1614-6154999

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155000

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 3'	System	28 Aug 2020 16:20:07

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:19', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0330b9d5-13a3-4d27-b191-af83261d123c'	System	30 Aug 2020 17:46:29
User entered 'Yes (Y)'	System	30 Aug 2020 17:46:29

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:22', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0330b9d5-13a3-4d27-b191-af83261d123c'	System	30 Aug 2020 17:46:29
User entered '98.5'	System	30 Aug 2020 17:46:29

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:25', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0330b9d5-13a3-4d27-b191-af83261d123c'	System	30 Aug 2020 17:46:29
User entered 'No (N)'	System	30 Aug 2020 17:46:29

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:26', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0330b9d5-13a3-4d27-b191-af83261d123c'	System	30 Aug 2020 17:46:29
User entered '30 Aug 2020 13:46'	System	30 Aug 2020 17:46:29

FDA-CBER-2022-1614-6155006

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155007

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155008

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 4'	System	28 Aug 2020 16:20:07

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:14', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '87692f5d-98ac-4ff3-816e-30499c6bf89d'	System	31 Aug 2020 16:08:28
User entered 'Yes (Y)'	System	31 Aug 2020 16:08:28

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:19', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '87692f5d-98ac-4ff3-816e-30499c6bf89d'	System	31 Aug 2020 16:08:28
User entered '97.6'	System	31 Aug 2020 16:08:28

FDA-CBER-2022-1614-6155011

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:22', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '87692f5d-98ac-4ff3-816e-30499c6bf89d'	System	31 Aug 2020 16:08:28
User entered 'No (N)'	System	31 Aug 2020 16:08:28

FDA-CBER-2022-1614-6155012

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:25', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '87692f5d-98ac-4ff3-816e-30499c6bf89d'	System	31 Aug 2020 16:08:28
User entered '31 Aug 2020 12:04'	System	31 Aug 2020 16:08:28

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155014

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155015

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 5'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155016

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:01:57', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '17697e38-9c17-4ba2-96dd-bbfbe73955e0'	System	01 Sep 2020 16:02:55
User entered 'Yes (Y)'	System	01 Sep 2020 16:02:55

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:01', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '17697e38-9c17-4ba2-96dd-bbfbe73955e0'	System	01 Sep 2020 16:02:55
User entered '97.9'	System	01 Sep 2020 16:02:55

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:04', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '17697e38-9c17-4ba2-96dd-bbfbe73955e0'	System	01 Sep 2020 16:02:55
User entered 'No (N)'	System	01 Sep 2020 16:02:55

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:07', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '17697e38-9c17-4ba2-96dd-bbfbe73955e0'	System	01 Sep 2020 16:02:55
User entered '01 Sep 2020 12:02'	System	01 Sep 2020 16:02:55

FDA-CBER-2022-1614-6155020

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155021

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155022

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 6'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155023

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b91242db-3159-440d-9ee7-f57b7ff3366c'	System	02 Sep 2020 16:04:01
User entered 'Yes (Y)'	System	02 Sep 2020 16:04:01

FDA-CBER-2022-1614-6155024

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:14', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b91242db-3159-440d-9ee7-f57b7ff3366c'	System	02 Sep 2020 16:04:01
User entered '97.6'	System	02 Sep 2020 16:04:01

FDA-CBER-2022-1614-6155025

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:17', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b91242db-3159-440d-9ee7-f57b7ff3366c'	System	02 Sep 2020 16:04:01
User entered 'No (N)'	System	02 Sep 2020 16:04:01

FDA-CBER-2022-1614-6155026

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:19', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b91242db-3159-440d-9ee7-f57b7ff3366c'	System	02 Sep 2020 16:04:01
User entered '02 Sep 2020 12:03'	System	02 Sep 2020 16:04:01

FDA-CBER-2022-1614-6155027

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155028

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155029

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 7'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155030

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:11:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:05:52', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7c93739c-97ea-4acc-9a8b-3e6b024aa342'	System	03 Sep 2020 16:07:30
User entered 'Yes (Y)'	System	03 Sep 2020 16:07:30

FDA-CBER-2022-1614-6155031

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:11:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:05:55', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7c93739c-97ea-4acc-9a8b-3e6b024aa342'	System	03 Sep 2020 16:07:30
User entered '98.5'	System	03 Sep 2020 16:07:30

FDA-CBER-2022-1614-6155032

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:11:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:05:58', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7c93739c-97ea-4acc-9a8b-3e6b024aa342'	System	03 Sep 2020 16:07:30
User entered 'No (N)'	System	03 Sep 2020 16:07:30

FDA-CBER-2022-1614-6155033

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7c93739c-97ea-4acc-9a8b-3e6b024aa342'	System	03 Sep 2020 16:07:30
User entered '03 Sep 2020 12:06'	System	03 Sep 2020 16:07:30

FDA-CBER-2022-1614-6155034

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155035

US3722066
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155036

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155037

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:21:43', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '54c6954a-f987-4576-b24c-1608b2d37424'	System	28 Aug 2020 16:22:45
User entered 'None (1)'	System	28 Aug 2020 16:22:45

FDA-CBER-2022-1614-6155038

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:21:49', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '54c6954a-f987-4576-b24c-1608b2d37424'	System	28 Aug 2020 16:22:45
User entered 'No (N)'	System	28 Aug 2020 16:22:45

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:22:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '54c6954a-f987-4576-b24c-1608b2d37424'	System	28 Aug 2020 16:22:45
User entered 'No (N)'	System	28 Aug 2020 16:22:45

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:22:40', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '54c6954a-f987-4576-b24c-1608b2d37424'	System	28 Aug 2020 16:22:45
User entered 'None (1)'	System	28 Aug 2020 16:22:45

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:22:42', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '54c6954a-f987-4576-b24c-1608b2d37424'	System	28 Aug 2020 16:22:45
User entered '28 Aug 2020 12:22'	System	28 Aug 2020 16:22:45

FDA-CBER-2022-1614-6155042

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:11'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155043

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 14:41'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155044

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155045

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:50:52', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'cc7b5ea2-3d64-44b8-895e-81d6a4ee4c4b'	System	28 Aug 2020 19:51:11
User entered 'None (1)'	System	28 Aug 2020 19:51:11

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:01', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'cc7b5ea2-3d64-44b8-895e-81d6a4ee4c4b'	System	28 Aug 2020 19:51:11
User entered 'No (N)'	System	28 Aug 2020 19:51:11

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:03', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'cc7b5ea2-3d64-44b8-895e-81d6a4ee4c4b'	System	28 Aug 2020 19:51:11
User entered 'No (N)'	System	28 Aug 2020 19:51:11

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:06', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'cc7b5ea2-3d64-44b8-895e-81d6a4ee4c4b'	System	28 Aug 2020 19:51:11
User entered 'None (1)'	System	28 Aug 2020 19:51:11

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:08', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'cc7b5ea2-3d64-44b8-895e-81d6a4ee4c4b'	System	28 Aug 2020 19:51:11
User entered '28 Aug 2020 15:51'	System	28 Aug 2020 19:51:11

FDA-CBER-2022-1614-6155050

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 15:36'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155051

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155052

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 2'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155053

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:29', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '514bc751-c657-4bf8-bffa-d450af41dda8'	System	30 Aug 2020 01:06:40
User entered 'None (1)'	System	30 Aug 2020 01:06:40

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:11:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:31', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '514bc751-c657-4bf8-bffa-d450af41dda8'	System	30 Aug 2020 01:06:40
User entered 'No (N)'	System	30 Aug 2020 01:06:40

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:11:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:33', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '514bc751-c657-4bf8-bffa-d450af41dda8'	System	30 Aug 2020 01:06:40
User entered 'No (N)'	System	30 Aug 2020 01:06:40

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '514bc751-c657-4bf8-bffa-d450af41dda8'	System	30 Aug 2020 01:06:40
User entered 'None (1)'	System	30 Aug 2020 01:06:40

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:38', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '514bc751-c657-4bf8-bffa-d450af41dda8'	System	30 Aug 2020 01:06:40
User entered '29 Aug 2020 21:06'	System	30 Aug 2020 01:06:40

FDA-CBER-2022-1614-6155058

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155059

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155060

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 3'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155061

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:30', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a758f844-858c-4735-b846-9b0f8e805cfe'	System	30 Aug 2020 17:46:40
User entered 'None (1)'	System	30 Aug 2020 17:46:40

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:11:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a758f844-858c-4735-b846-9b0f8e805cfe'	System	30 Aug 2020 17:46:40
User entered 'No (N)'	System	30 Aug 2020 17:46:40

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:11:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:33', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a758f844-858c-4735-b846-9b0f8e805cfe'	System	30 Aug 2020 17:46:40
User entered 'No (N)'	System	30 Aug 2020 17:46:40

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a758f844-858c-4735-b846-9b0f8e805cfe'	System	30 Aug 2020 17:46:40
User entered 'None (1)'	System	30 Aug 2020 17:46:40

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:38', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a758f844-858c-4735-b846-9b0f8e805cfe'	System	30 Aug 2020 17:46:40
User entered '30 Aug 2020 13:46'	System	30 Aug 2020 17:46:40

FDA-CBER-2022-1614-6155066

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155067

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155068

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 4'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155069

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:30', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0618fe36-e115-4504-9284-9b8d96ab486c'	System	31 Aug 2020 16:08:48
User entered 'None (1)'	System	31 Aug 2020 16:08:48

FDA-CBER-2022-1614-6155070

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:11:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0618fe36-e115-4504-9284-9b8d96ab486c'	System	31 Aug 2020 16:08:48
User entered 'No (N)'	System	31 Aug 2020 16:08:48

FDA-CBER-2022-1614-6155071

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:11:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:34', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0618fe36-e115-4504-9284-9b8d96ab486c'	System	31 Aug 2020 16:08:48
User entered 'No (N)'	System	31 Aug 2020 16:08:48

FDA-CBER-2022-1614-6155072

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0618fe36-e115-4504-9284-9b8d96ab486c'	System	31 Aug 2020 16:08:48
User entered 'None (1)'	System	31 Aug 2020 16:08:48

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:38', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0618fe36-e115-4504-9284-9b8d96ab486c'	System	31 Aug 2020 16:08:48
User entered '31 Aug 2020 12:04'	System	31 Aug 2020 16:08:48

FDA-CBER-2022-1614-6155074

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155075

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155076

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 5'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155077

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd8487881-2f8e-4ffb-a19d-90efdffec612'	System	01 Sep 2020 16:03:08
User entered 'None (1)'	System	01 Sep 2020 16:03:08

FDA-CBER-2022-1614-6155078

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:11:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:12', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd8487881-2f8e-4ffb-a19d-90efdffec612'	System	01 Sep 2020 16:03:08
User entered 'No (N)'	System	01 Sep 2020 16:03:08

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:11:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:15', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd8487881-2f8e-4ffb-a19d-90efdffec612'	System	01 Sep 2020 16:03:08
User entered 'No (N)'	System	01 Sep 2020 16:03:08

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:18', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd8487881-2f8e-4ffb-a19d-90efdffec612'	System	01 Sep 2020 16:03:08
User entered 'None (1)'	System	01 Sep 2020 16:03:08

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:20', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd8487881-2f8e-4ffb-a19d-90efdffec612'	System	01 Sep 2020 16:03:08
User entered '01 Sep 2020 12:02'	System	01 Sep 2020 16:03:08

FDA-CBER-2022-1614-6155082

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155083

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155084

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 6'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155085

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:23', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '47da36b6-fcea-4d58-8bfc-79e42e3cb5de'	System	02 Sep 2020 16:04:14
User entered 'None (1)'	System	02 Sep 2020 16:04:14

FDA-CBER-2022-1614-6155086

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:11:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:26', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '47da36b6-fcea-4d58-8bfc-79e42e3cb5de'	System	02 Sep 2020 16:04:14
User entered 'No (N)'	System	02 Sep 2020 16:04:14

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:11:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '47da36b6-fcea-4d58-8bfc-79e42e3cb5de'	System	02 Sep 2020 16:04:14
User entered 'No (N)'	System	02 Sep 2020 16:04:14

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:31', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '47da36b6-fcea-4d58-8bfc-79e42e3cb5de'	System	02 Sep 2020 16:04:14
User entered 'None (1)'	System	02 Sep 2020 16:04:14

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '47da36b6-fcea-4d58-8bfc-79e42e3cb5de'	System	02 Sep 2020 16:04:14
User entered '02 Sep 2020 12:03'	System	02 Sep 2020 16:04:14

FDA-CBER-2022-1614-6155090

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155091

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155092

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 7'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155093

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '805d6a37-e3b1-4fd2-acad-09573ca02838'	System	03 Sep 2020 16:07:41
User entered 'None (1)'	System	03 Sep 2020 16:07:41

FDA-CBER-2022-1614-6155094

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:11:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:07', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '805d6a37-e3b1-4fd2-acad-09573ca02838'	System	03 Sep 2020 16:07:41
User entered 'No (N)'	System	03 Sep 2020 16:07:41

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:11:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '805d6a37-e3b1-4fd2-acad-09573ca02838'	System	03 Sep 2020 16:07:41
User entered 'No (N)'	System	03 Sep 2020 16:07:41

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:11', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '805d6a37-e3b1-4fd2-acad-09573ca02838'	System	03 Sep 2020 16:07:41
User entered 'None (1)'	System	03 Sep 2020 16:07:41

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:11:02
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:14', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '805d6a37-e3b1-4fd2-acad-09573ca02838'	System	03 Sep 2020 16:07:41
User entered '03 Sep 2020 12:06'	System	03 Sep 2020 16:07:41

FDA-CBER-2022-1614-6155098

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155099

US3722066
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155100

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155101

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:22:46', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b8ffeb59-d91f-4a9d-8925-3e75447e5c7b'	System	28 Aug 2020 16:23:08
User entered 'None (0)'	System	28 Aug 2020 16:23:08

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:22:48', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b8ffeb59-d91f-4a9d-8925-3e75447e5c7b'	System	28 Aug 2020 16:23:08
User entered 'None (0)'	System	28 Aug 2020 16:23:08

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:22:51', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b8ffeb59-d91f-4a9d-8925-3e75447e5c7b'	System	28 Aug 2020 16:23:08
User entered 'None (0)'	System	28 Aug 2020 16:23:08

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:22:53', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b8ffeb59-d91f-4a9d-8925-3e75447e5c7b'	System	28 Aug 2020 16:23:08
User entered 'None (0)'	System	28 Aug 2020 16:23:08

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:22:56', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b8ffeb59-d91f-4a9d-8925-3e75447e5c7b'	System	28 Aug 2020 16:23:08
User entered 'None (0)'	System	28 Aug 2020 16:23:08

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:22:58', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b8ffeb59-d91f-4a9d-8925-3e75447e5c7b'	System	28 Aug 2020 16:23:08
User entered 'None (0)'	System	28 Aug 2020 16:23:08

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:23:02', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b8ffeb59-d91f-4a9d-8925-3e75447e5c7b'	System	28 Aug 2020 16:23:08
User entered 'No (N)'	System	28 Aug 2020 16:23:08

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:23:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b8ffeb59-d91f-4a9d-8925-3e75447e5c7b'	System	28 Aug 2020 16:23:08
User entered '28 Aug 2020 12:23'	System	28 Aug 2020 16:23:08

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:11'	System	28 Aug 2020 16:20:07

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 14:41'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155111

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155112

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:14', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ca854bfa-e86f-45d6-95c8-066e49b0a9da'	System	28 Aug 2020 19:51:30
User entered 'None (0)'	System	28 Aug 2020 19:51:30

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:16', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ca854bfa-e86f-45d6-95c8-066e49b0a9da'	System	28 Aug 2020 19:51:30
User entered 'None (0)'	System	28 Aug 2020 19:51:30

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:17', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ca854bfa-e86f-45d6-95c8-066e49b0a9da'	System	28 Aug 2020 19:51:30
User entered 'None (0)'	System	28 Aug 2020 19:51:30

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:19', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ca854bfa-e86f-45d6-95c8-066e49b0a9da'	System	28 Aug 2020 19:51:30
User entered 'None (0)'	System	28 Aug 2020 19:51:30

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:21', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ca854bfa-e86f-45d6-95c8-066e49b0a9da'	System	28 Aug 2020 19:51:30
User entered 'None (0)'	System	28 Aug 2020 19:51:30

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:23', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ca854bfa-e86f-45d6-95c8-066e49b0a9da'	System	28 Aug 2020 19:51:30
User entered 'None (0)'	System	28 Aug 2020 19:51:30

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:26', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ca854bfa-e86f-45d6-95c8-066e49b0a9da'	System	28 Aug 2020 19:51:30
User entered 'No (N)'	System	28 Aug 2020 19:51:30

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ca854bfa-e86f-45d6-95c8-066e49b0a9da'	System	28 Aug 2020 19:51:30
User entered '28 Aug 2020 15:51'	System	28 Aug 2020 19:51:30

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 15:36'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155121

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 2'	System	28 Aug 2020 16:20:07

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:42', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ed0b0203-00ea-4f44-8e19-2746f2f87a65'	System	30 Aug 2020 01:06:59
User entered 'None (0)'	System	30 Aug 2020 01:06:59

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:43', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ed0b0203-00ea-4f44-8e19-2746f2f87a65'	System	30 Aug 2020 01:06:59
User entered 'None (0)'	System	30 Aug 2020 01:06:59

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:45', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ed0b0203-00ea-4f44-8e19-2746f2f87a65'	System	30 Aug 2020 01:06:59
User entered 'None (0)'	System	30 Aug 2020 01:06:59

FDA-CBER-2022-1614-6155126

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:47', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ed0b0203-00ea-4f44-8e19-2746f2f87a65'	System	30 Aug 2020 01:06:59
User entered 'None (0)'	System	30 Aug 2020 01:06:59

FDA-CBER-2022-1614-6155127

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:49', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ed0b0203-00ea-4f44-8e19-2746f2f87a65'	System	30 Aug 2020 01:06:59
User entered 'None (0)'	System	30 Aug 2020 01:06:59

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:50', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ed0b0203-00ea-4f44-8e19-2746f2f87a65'	System	30 Aug 2020 01:06:59
User entered 'None (0)'	System	30 Aug 2020 01:06:59

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:53', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ed0b0203-00ea-4f44-8e19-2746f2f87a65'	System	30 Aug 2020 01:06:59
User entered 'No (N)'	System	30 Aug 2020 01:06:59

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:55', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ed0b0203-00ea-4f44-8e19-2746f2f87a65'	System	30 Aug 2020 01:06:59
User entered '29 Aug 2020 21:06'	System	30 Aug 2020 01:06:59

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155132

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155133

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 3'	System	28 Aug 2020 16:20:07

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:42', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a038e983-38ad-4db7-83f0-ed85cafca2b7'	System	30 Aug 2020 17:46:57
User entered 'None (0)'	System	30 Aug 2020 17:46:57

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:44', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a038e983-38ad-4db7-83f0-ed85cafca2b7'	System	30 Aug 2020 17:46:57
User entered 'None (0)'	System	30 Aug 2020 17:46:57

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:46', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a038e983-38ad-4db7-83f0-ed85cafca2b7'	System	30 Aug 2020 17:46:57
User entered 'None (0)'	System	30 Aug 2020 17:46:57

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:47', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a038e983-38ad-4db7-83f0-ed85cafca2b7'	System	30 Aug 2020 17:46:57
User entered 'None (0)'	System	30 Aug 2020 17:46:57

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:49', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a038e983-38ad-4db7-83f0-ed85cafca2b7'	System	30 Aug 2020 17:46:57
User entered 'None (0)'	System	30 Aug 2020 17:46:57

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:50', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a038e983-38ad-4db7-83f0-ed85cafca2b7'	System	30 Aug 2020 17:46:57
User entered 'None (0)'	System	30 Aug 2020 17:46:57

FDA-CBER-2022-1614-6155140

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:53', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a038e983-38ad-4db7-83f0-ed85cafca2b7'	System	30 Aug 2020 17:46:57
User entered 'No (N)'	System	30 Aug 2020 17:46:57

FDA-CBER-2022-1614-6155141

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:55', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a038e983-38ad-4db7-83f0-ed85cafca2b7'	System	30 Aug 2020 17:46:57
User entered '30 Aug 2020 13:46'	System	30 Aug 2020 17:46:57

FDA-CBER-2022-1614-6155142

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155143

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155144

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 4'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155145

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:43', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '61505483-51fd-4f75-a043-9f8bb0605b7e'	System	31 Aug 2020 16:09:00
User entered 'None (0)'	System	31 Aug 2020 16:09:00

FDA-CBER-2022-1614-6155146

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:45', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '61505483-51fd-4f75-a043-9f8bb0605b7e'	System	31 Aug 2020 16:09:00
User entered 'None (0)'	System	31 Aug 2020 16:09:00

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:46', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '61505483-51fd-4f75-a043-9f8bb0605b7e'	System	31 Aug 2020 16:09:00
User entered 'None (0)'	System	31 Aug 2020 16:09:00

FDA-CBER-2022-1614-6155148

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:48', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '61505483-51fd-4f75-a043-9f8bb0605b7e'	System	31 Aug 2020 16:09:00
User entered 'None (0)'	System	31 Aug 2020 16:09:00

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:50', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '61505483-51fd-4f75-a043-9f8bb0605b7e'	System	31 Aug 2020 16:09:00
User entered 'None (0)'	System	31 Aug 2020 16:09:00

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:52', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '61505483-51fd-4f75-a043-9f8bb0605b7e'	System	31 Aug 2020 16:09:00
User entered 'None (0)'	System	31 Aug 2020 16:09:00

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:55', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '61505483-51fd-4f75-a043-9f8bb0605b7e'	System	31 Aug 2020 16:09:00
User entered 'No (N)'	System	31 Aug 2020 16:09:00

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:57', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '61505483-51fd-4f75-a043-9f8bb0605b7e'	System	31 Aug 2020 16:09:00
User entered '31 Aug 2020 12:04'	System	31 Aug 2020 16:09:00

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155154

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155155

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 5'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155156

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:23', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a3e5aa52-802b-486d-968d-9348cef3330f'	System	01 Sep 2020 16:03:21
User entered 'None (0)'	System	01 Sep 2020 16:03:21

FDA-CBER-2022-1614-6155157

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:25', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a3e5aa52-802b-486d-968d-9348cef3330f'	System	01 Sep 2020 16:03:21
User entered 'None (0)'	System	01 Sep 2020 16:03:21

FDA-CBER-2022-1614-6155158

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:26', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a3e5aa52-802b-486d-968d-9348cef3330f'	System	01 Sep 2020 16:03:21
User entered 'None (0)'	System	01 Sep 2020 16:03:21

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a3e5aa52-802b-486d-968d-9348cef3330f'	System	01 Sep 2020 16:03:21
User entered 'None (0)'	System	01 Sep 2020 16:03:21

FDA-CBER-2022-1614-6155160

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:30', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a3e5aa52-802b-486d-968d-9348cef3330f'	System	01 Sep 2020 16:03:21
User entered 'None (0)'	System	01 Sep 2020 16:03:21

FDA-CBER-2022-1614-6155161

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a3e5aa52-802b-486d-968d-9348cef3330f'	System	01 Sep 2020 16:03:21
User entered 'None (0)'	System	01 Sep 2020 16:03:21

FDA-CBER-2022-1614-6155162

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:34', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a3e5aa52-802b-486d-968d-9348cef3330f'	System	01 Sep 2020 16:03:21
User entered 'No (N)'	System	01 Sep 2020 16:03:21

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a3e5aa52-802b-486d-968d-9348cef3330f'	System	01 Sep 2020 16:03:21
User entered '01 Sep 2020 12:02'	System	01 Sep 2020 16:03:21

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 16:20:07

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155166

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 6'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155167

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:39', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '71f5cf57-b0f6-4c26-9db8-ad98abc33a92'	System	02 Sep 2020 16:04:24
User entered 'None (0)'	System	02 Sep 2020 16:04:24

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '71f5cf57-b0f6-4c26-9db8-ad98abc33a92'	System	02 Sep 2020 16:04:24
User entered 'None (0)'	System	02 Sep 2020 16:04:24

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:43', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '71f5cf57-b0f6-4c26-9db8-ad98abc33a92'	System	02 Sep 2020 16:04:24
User entered 'None (0)'	System	02 Sep 2020 16:04:24

FDA-CBER-2022-1614-6155170

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:44', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '71f5cf57-b0f6-4c26-9db8-ad98abc33a92'	System	02 Sep 2020 16:04:24
User entered 'None (0)'	System	02 Sep 2020 16:04:24

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:46', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '71f5cf57-b0f6-4c26-9db8-ad98abc33a92'	System	02 Sep 2020 16:04:24
User entered 'None (0)'	System	02 Sep 2020 16:04:24

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:48', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '71f5cf57-b0f6-4c26-9db8-ad98abc33a92'	System	02 Sep 2020 16:04:24
User entered 'None (0)'	System	02 Sep 2020 16:04:24

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:50', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '71f5cf57-b0f6-4c26-9db8-ad98abc33a92'	System	02 Sep 2020 16:04:24
User entered 'No (N)'	System	02 Sep 2020 16:04:24

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:52', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '71f5cf57-b0f6-4c26-9db8-ad98abc33a92'	System	02 Sep 2020 16:04:24
User entered '02 Sep 2020 12:03'	System	02 Sep 2020 16:04:24

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155176

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155177

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 7'	System	28 Aug 2020 16:20:07

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:18', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b26a2e88-f235-4ca1-83cb-1ec231bdf791'	System	03 Sep 2020 16:07:52
User entered 'None (0)'	System	03 Sep 2020 16:07:52

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:27', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b26a2e88-f235-4ca1-83cb-1ec231bdf791'	System	03 Sep 2020 16:07:52
User entered 'None (0)'	System	03 Sep 2020 16:07:52

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:30', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b26a2e88-f235-4ca1-83cb-1ec231bdf791'	System	03 Sep 2020 16:07:52
User entered 'None (0)'	System	03 Sep 2020 16:07:52

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:33', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b26a2e88-f235-4ca1-83cb-1ec231bdf791'	System	03 Sep 2020 16:07:52
User entered 'None (0)'	System	03 Sep 2020 16:07:52

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:35', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b26a2e88-f235-4ca1-83cb-1ec231bdf791'	System	03 Sep 2020 16:07:52
User entered 'None (0)'	System	03 Sep 2020 16:07:52

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:37', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b26a2e88-f235-4ca1-83cb-1ec231bdf791'	System	03 Sep 2020 16:07:52
User entered 'None (0)'	System	03 Sep 2020 16:07:52

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:40', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b26a2e88-f235-4ca1-83cb-1ec231bdf791'	System	03 Sep 2020 16:07:52
User entered 'No (N)'	System	03 Sep 2020 16:07:52

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b26a2e88-f235-4ca1-83cb-1ec231bdf791'	System	03 Sep 2020 16:07:52
User entered '03 Sep 2020 12:06'	System	03 Sep 2020 16:07:52

FDA-CBER-2022-1614-6155186

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
PC Open Date & Time

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 16:20:07

FDA-CBER-2022-1614-6155187

US3722066
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:11:02
PC Close Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Sep 2020 18:59:51

FDA-CBER-2022-1614-6155189

US3722066
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '7 Sep 2020'	Kayla Peay (b) (4) (b) (4)	11 Sep 2020 18:59:51

FDA-CBER-2022-1614-6155190

US3722066
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4) (b) (4)	11 Sep 2020 18:59:51

FDA-CBER-2022-1614-6155191

US3722066
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Sep 2020 18:59:51

FDA-CBER-2022-1614-6155192

US3722066
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Sep 2020 18:59:54

FDA-CBER-2022-1614-6155193

US3722066
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 18:59:54

FDA-CBER-2022-1614-6155194

US3722066
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Sep 2020 19:00:06

FDA-CBER-2022-1614-6155195

US3722066
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Kayla Peay (b) (4) (b) (4)	11 Sep 2020 19:00:06

FDA-CBER-2022-1614-6155196

US3722066
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4) (b) (4)	11 Sep 2020 19:00:06

FDA-CBER-2022-1614-6155197

US3722066
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Sep 2020 19:00:06

FDA-CBER-2022-1614-6155198

US3722066
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Sep 2020 19:00:11

FDA-CBER-2022-1614-6155199

US3722066
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 19:00:11

FDA-CBER-2022-1614-6155200

US3722066
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	18 Sep 2020 17:35:13

FDA-CBER-2022-1614-6155201

US3722066
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Kayla Peay (b) (4) (b) (4)	18 Sep 2020 17:35:13

FDA-CBER-2022-1614-6155202

US3722066
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4) (b) (4)	18 Sep 2020 17:35:13

FDA-CBER-2022-1614-6155203

US3722066
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	18 Sep 2020 17:35:13

FDA-CBER-2022-1614-6155204

US3722066
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	18 Sep 2020 17:35:16

FDA-CBER-2022-1614-6155205

US3722066
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:35:16

FDA-CBER-2022-1614-6155206

US3722066
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02
Was this visit performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 14:48:02

FDA-CBER-2022-1614-6155207

US3722066
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 14:48:02

FDA-CBER-2022-1614-6155208

US3722066
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 14:48:02

FDA-CBER-2022-1614-6155209

US3722066
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02
Folder OID

Audit	User	Time (GMT)
User entered 'VISIT3'	System	25 Sep 2020 14:48:02

FDA-CBER-2022-1614-6155210

US3722066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 14:48:28

FDA-CBER-2022-1614-6155211

US3722066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 14:48:28

FDA-CBER-2022-1614-6155212

US3722066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '09:01'	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 14:48:28

FDA-CBER-2022-1614-6155213

US3722066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '25 Sep 2020 09:01'	System	25 Sep 2020 14:48:28

US3722066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User entered '98.4' F	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 14:48:28

FDA-CBER-2022-1614-6155215

US3722066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Route of measurement

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 14:48:28

FDA-CBER-2022-1614-6155216

US3722066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
If Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 14:48:28

FDA-CBER-2022-1614-6155217

US3722066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Pulse *(xxx)*

Audit	User	Time (GMT)
User entered '69'	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 14:48:28

FDA-CBER-2022-1614-6155218

US3722066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Sep 2020 14:48:28

FDA-CBER-2022-1614-6155219

US3722066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User entered '16'	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 14:48:28

FDA-CBER-2022-1614-6155220

US3722066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Sep 2020 14:48:28

FDA-CBER-2022-1614-6155221

US3722066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '143'	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 14:48:28

FDA-CBER-2022-1614-6155222

US3722066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 14:48:28

FDA-CBER-2022-1614-6155223

US3722066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '81'	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 14:48:28

FDA-CBER-2022-1614-6155224

US3722066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 14:48:28

FDA-CBER-2022-1614-6155225

US3722066
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:11:02
Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 14:48:33

FDA-CBER-2022-1614-6155226

US3722066
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:11:02
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 14:48:33

FDA-CBER-2022-1614-6155227

US3722066
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:11:02
Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 14:48:42

FDA-CBER-2022-1614-6155228

US3722066
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:11:02
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 14:48:42

FDA-CBER-2022-1614-6155229

US3722066
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:11:02
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '09:38'	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 14:48:42

FDA-CBER-2022-1614-6155230

US3722066
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:11:02
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '25 Sep 2020 09:38'	System	25 Sep 2020 14:48:42

US3722066
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 14:48:45

FDA-CBER-2022-1614-6155232

US3722066
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 14:48:45

FDA-CBER-2022-1614-6155233

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 64'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6155234

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:02

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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-03T11:19:16', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0aaa5a2e-bd7e-4ac7-9a1f-d064597b5101'	System	03 Oct 2020 15:19:29
User entered 'No (N)'	System	03 Oct 2020 15:19:29

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:02

Have you been exposed to someone with 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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-03T11:19:23', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0aaa5a2e-bd7e-4ac7-9a1f-d064597b5101'	System	03 Oct 2020 15:19:29
User entered 'No (N)'	System	03 Oct 2020 15:19:29

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-03T11:19:27', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0aaa5a2e-bd7e-4ac7-9a1f-d064597b5101'	System	03 Oct 2020 15:19:29
User entered '03 Oct 2020 11:19:27'	System	03 Oct 2020 15:19:29

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '03 Oct 2020 00:01'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6155238

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '07 Oct 2020 23:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6155239

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 71'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6155240

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:02

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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-10T00:07:31', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a3ae19-2aef-4b96-ac3c-7cb5308197f8'	System	10 Oct 2020 04:07:41
User entered 'No (N)'	System	10 Oct 2020 04:07:41

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:02

Have you been exposed to someone with 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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-10T00:07:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a3ae19-2aef-4b96-ac3c-7cb5308197f8'	System	10 Oct 2020 04:07:41
User entered 'No (N)'	System	10 Oct 2020 04:07:41

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-10T00:07:39', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a3ae19-2aef-4b96-ac3c-7cb5308197f8'	System	10 Oct 2020 04:07:41
User entered '10 Oct 2020 00:07:39'	System	10 Oct 2020 04:07:41

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '10 Oct 2020 00:01'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6155244

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '14 Oct 2020 23:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6155245

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 78'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6155246

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:02

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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-17T15:05:23', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'dac4aa5d-297c-486d-a6fa-777ea2255bb6'	System	17 Oct 2020 19:05:38
User entered 'No (N)'	System	17 Oct 2020 19:05:38

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:02

Have you been exposed to someone with 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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-17T15:05:30', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'dac4aa5d-297c-486d-a6fa-777ea2255bb6'	System	17 Oct 2020 19:05:38
User entered 'No (N)'	System	17 Oct 2020 19:05:38

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-17T15:05:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'dac4aa5d-297c-486d-a6fa-777ea2255bb6'	System	17 Oct 2020 19:05:38
User entered '17 Oct 2020 15:05:32'	System	17 Oct 2020 19:05:38

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '17 Oct 2020 00:01'	System	03 Aug 2020 21:49:25

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '21 Oct 2020 23:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6155251

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 92'	System	03 Aug 2020 21:49:25

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:02

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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-31T02:13:14', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '524bfdaa-0ca4-449a-b61c-fa7bda85758b'	System	31 Oct 2020 07:13:37
User entered 'No (N)'	System	31 Oct 2020 07:13:37

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:02

Have you been exposed to someone with 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 (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-31T02:13:29', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '524bfdaa-0ca4-449a-b61c-fa7bda85758b'	System	31 Oct 2020 07:13:37
User entered 'No (N)'	System	31 Oct 2020 07:13:37

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-31T02:13:34', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '524bfdaa-0ca4-449a-b61c-fa7bda85758b'	System	31 Oct 2020 07:13:37
User entered '31 Oct 2020 02:13:34'	System	31 Oct 2020 07:13:37

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '31 Oct 2020 00:01'	System	03 Aug 2020 21:49:25

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '04 Nov 2020 23:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6155257

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 106'	System	03 Aug 2020 21:49:25

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:02

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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:25:04', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered 'Yes (Y)'	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:02

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:25:17', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered 'No (N)'	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:02

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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:25:26', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered 'Yes (Y)'	System	14 Nov 2020 05:27:14

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered '1'	System	14 Nov 2020 05:27:14

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Chills

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered '1'	System	14 Nov 2020 05:27:14

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Cough

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered '1'	System	14 Nov 2020 05:27:14

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Shortness of breath

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered '1'	System	14 Nov 2020 05:27:14

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Difficulty breathing

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered '0'	System	14 Nov 2020 05:27:14

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Fatigue

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered '1'	System	14 Nov 2020 05:27:14

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Muscle aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered '1'	System	14 Nov 2020 05:27:14

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Body aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered '1'	System	14 Nov 2020 05:27:14

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Headache

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered '1'	System	14 Nov 2020 05:27:14

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
New loss of taste

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered '0'	System	14 Nov 2020 05:27:14

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
New loss of smell

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered '0'	System	14 Nov 2020 05:27:14

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Sore throat

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered '0'	System	14 Nov 2020 05:27:14

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Congestion

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered '0'	System	14 Nov 2020 05:27:14

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Runny nose

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered '0'	System	14 Nov 2020 05:27:14

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Nausea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered '0'	System	14 Nov 2020 05:27:14

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Vomiting

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered '0'	System	14 Nov 2020 05:27:14

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Diarrhea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered '0'	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:02

Please 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:19', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:02

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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:59', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered 'No (N)'	System	14 Nov 2020 05:27:14

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:27:04', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered '14 Nov 2020 00:27:04'	System	14 Nov 2020 05:27:14

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '14 Nov 2020 00:01'	System	03 Aug 2020 21:49:25

US3722066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '18 Nov 2020 23:59'	System	03 Aug 2020 21:49:25

FDA-CBER-2022-1614-6155283

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155284

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '30 Sep 2020 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155285

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '04 Oct 2020 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155286

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155287

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '07 Oct 2020 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155288

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '11 Oct 2020 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155289

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155290

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '14 Oct 2020 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155291

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '18 Oct 2020 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155292

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155293

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '21 Oct 2020 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155294

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '25 Oct 2020 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155295

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155296

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '28 Oct 2020 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155297

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '01 Nov 2020 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155298

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155299

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '04 Nov 2020 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155300

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '08 Nov 2020 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155301

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155302

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '11 Nov 2020 00:01'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '15 Nov 2020 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155304

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155305

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:02

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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T08:59:17', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered 'Yes (Y)'	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:02

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T08:59:34', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered 'No (N)'	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:02

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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T08:59:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered 'Yes (Y)'	System	21 Nov 2020 14:00:47

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered '0'	System	21 Nov 2020 14:00:47

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Chills

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered '0'	System	21 Nov 2020 14:00:47

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Cough

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered '1'	System	21 Nov 2020 14:00:47

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Shortness of breath

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered '1'	System	21 Nov 2020 14:00:47

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Difficulty breathing

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered '1'	System	21 Nov 2020 14:00:47

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Fatigue

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered '1'	System	21 Nov 2020 14:00:47

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Muscle aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered '0'	System	21 Nov 2020 14:00:47

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Body aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered '0'	System	21 Nov 2020 14:00:47

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Headache

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered '0'	System	21 Nov 2020 14:00:47

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
New loss of taste

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered '0'	System	21 Nov 2020 14:00:47

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
New loss of smell

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered '0'	System	21 Nov 2020 14:00:47

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Sore throat

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered '0'	System	21 Nov 2020 14:00:47

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Congestion

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered '0'	System	21 Nov 2020 14:00:47

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Runny nose

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered '0'	System	21 Nov 2020 14:00:47

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Nausea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered '0'	System	21 Nov 2020 14:00:47

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Vomiting

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered '0'	System	21 Nov 2020 14:00:47

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Diarrhea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered '1'	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:02

Please 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:17', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:02

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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:22', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered 'Yes (Y)'	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:02

Please 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Nov 2020 14:00:47

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered '21 Nov 2020 09:00:32'	System	21 Nov 2020 14:00:47

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155330

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155331

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155332

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155333

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155335

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155336

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155337

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155338

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155339

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155340

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155341

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155342

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155343

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155344

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155345

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155346

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155347

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155348

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155349

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155350

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155351

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155352

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155353

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155354

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155356

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155357

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155358

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155359

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155360

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155361

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155362

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155363

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155364

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155366

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155367

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155368

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155369

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155370

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155371

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155373

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155374

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155375

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155376

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155377

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155378

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155379

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155380

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155381

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155382

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155383

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155384

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155385

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155386

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155387

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155389

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155390

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155391

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155392

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155394

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155395

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155396

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155397

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155398

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155399

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155400

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155401

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155402

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155403

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155404

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155405

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155406

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155407

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155408

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155409

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155410

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155411

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155412

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155413

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155414

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155415

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155416

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155417

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155418

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155419

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155420

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155421

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155422

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155424

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155425

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155426

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155427

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155428

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155429

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155430

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155431

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155432

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155433

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155434

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155435

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155436

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155437

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155438

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155439

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155440

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155441

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155442

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155443

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155444

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155445

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155446

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155447

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155448

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155449

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155450

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155451

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155452

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155454

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155455

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155456

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155457

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155458

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155459

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155460

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155461

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155462

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155463

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155464

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155466

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155467

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155468

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155469

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155470

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155471

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155472

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155473

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155474

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155475

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155476

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155477

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155478

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155479

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155480

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155481

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155482

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155483

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155484

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155485

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155486

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155487

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155488

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155489

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155490

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155491

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155492

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155493

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155494

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155495

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155496

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155497

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155498

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155499

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155500

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155501

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155502

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155503

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155506

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155507

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155508

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155509

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155510

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155511

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155512

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155513

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155514

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155515

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155516

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155517

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155518

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155519

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155520

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155521

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155522

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155523

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155524

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155525

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155526

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155527

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155528

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155529

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155530

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155531

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155532

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155533

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155534

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155535

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155536

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155537

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155539

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155540

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155541

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155542

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155543

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155544

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155545

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155546

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155547

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155548

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155549

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155551

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155552

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155554

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155556

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155557

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155558

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155559

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155560

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155561

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155562

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155563

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155564

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155566

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155567

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155570

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155571

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155572

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155573

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155574

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155575

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155576

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155577

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155578

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155579

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155580

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155581

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155582

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155584

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155585

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155586

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155587

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155588

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155589

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155590

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155591

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155593

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155596

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155598

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155599

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155600

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155602

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155603

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155604

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155606

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155608

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155609

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155610

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155611

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155612

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155614

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155615

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155616

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155617

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155618

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155619

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155620

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155621

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155622

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155623

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:11:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 12:05:39

FDA-CBER-2022-1614-6155625

US3722066
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	05 Nov 2020 18:32:15

FDA-CBER-2022-1614-6155626

US3722066
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Marlee Smith (b) (4) (b) (4)	05 Nov 2020 18:32:15

FDA-CBER-2022-1614-6155627

US3722066
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Marlee Smith (b) (4) (b) (4)	05 Nov 2020 18:32:15

FDA-CBER-2022-1614-6155628

US3722066
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Marlee Smith (b) (4) (b) (4)	05 Nov 2020 18:32:15

FDA-CBER-2022-1614-6155629

US3722066
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	05 Nov 2020 18:32:17

FDA-CBER-2022-1614-6155630

US3722066
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 18:32:17

FDA-CBER-2022-1614-6155631

US3722066
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	16 Nov 2020 14:17:44

FDA-CBER-2022-1614-6155632

US3722066
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Sara Poff (b) (4) (b) (4)	16 Nov 2020 14:17:44

FDA-CBER-2022-1614-6155633

US3722066
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sara Poff (b) (4) (b) (4)	16 Nov 2020 14:17:44

FDA-CBER-2022-1614-6155634

US3722066
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:11:02
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Subject reported SOB, fever of 102.6 and muscle aches. Subject has been scheduled for a sick visit.'	Sara Poff (b) (4) (b) (4)	16 Nov 2020 14:17:44

FDA-CBER-2022-1614-6155635

US3722066
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	16 Nov 2020 14:17:54

FDA-CBER-2022-1614-6155636

US3722066
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:11:02
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 14:17:54

FDA-CBER-2022-1614-6155637

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: COVID-19 Contact
Generated On: 26 Nov 2020 11:11:02
Date of Contact

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:52:11
User closed query 'Please reconcile and enter missing severity page' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:35:12
Query 'Please reconcile and enter missing severity page' answered with 'Completed ' (Site from CRA).	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:52:53
User opened query 'Please reconcile and enter missing severity page' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:54:59
User entered '16 Nov 2020'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:45:14

FDA-CBER-2022-1614-6155638

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: COVID-19 Contact
Generated On: 26 Nov 2020 11:11:02
Time of Contact

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:33:15
User closed query 'Please verify time of contact, as first time entry in source appears to be 15:16.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 02:33:13
Query 'Please verify time of contact, as first time entry in source appears to be 15:16.' answered with 'Updated ' (Site from CRA).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:32:52
User entered '15:16' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:32:45
User opened query 'Please verify time of contact, as first time entry in source appears to be 15:16.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:54:29
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 20:52:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:52:11
User entered '15:20'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:45:14

FDA-CBER-2022-1614-6155639

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: COVID-19 Contact
Generated On: 26 Nov 2020 11:11:02
Date and Time of Contact (derived)

Audit	User	Time (GMT)
User entered '16 Nov 2020 15:16'	System	24 Nov 2020 00:32:45
User entered '16 Nov 2020 15:20'	System	18 Nov 2020 19:45:14

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: COVID-19 Contact
Generated On: 26 Nov 2020 11:11:02
Type of Contact

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:52:11
User entered 'Clinic Visit - Scheduled (Clinic Visit Scheduled)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:45:14

FDA-CBER-2022-1614-6155641

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: COVID-19 Contact
Generated On: 26 Nov 2020 11:11:02
Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:52:11
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:45:14

FDA-CBER-2022-1614-6155642

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:41:25
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31
User entered 'Day 1 (Day 1)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
Date

Audit	User	Time (GMT)
User closed query 'Please comment and clarify on the lack of diary entries from 17 Nov 2020 and forward. If the lack of completion is related to the subject's hospitalization, please confirm in query response if contacts with the site have occurred and their context.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 03:59:26
User closed query 'Thank you for your previous response. Please note that symptoms should be captured starting 11 NOV 2020 based on the start date of the initial AE. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 03:59:19
Query 'Thank you for your previous response. Please note that symptoms should be captured starting 11 NOV 2020 based on the start date of the initial AE. ' answered with 'updated ' (Site from CRA).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:34:18
Query 'Please comment and clarify on the lack of diary entries from 17 Nov 2020 and forward. If the lack of completion is related to the subject's hospitalization, please confirm in query response if contacts with the site have occurred and their context.' answered with 'The reason for the lack of diary entries is due to the hospitalization ' (Site from CRA).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:34:01
User opened query 'Please comment and clarify on the lack of diary entries from 17 Nov 2020 and forward. If the lack of completion is related to the subject's hospitalization, please confirm in query response if contacts with the site have occurred and their context.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:18:11
User opened query 'Thank you for your previous response. Please note that symptoms should be captured starting 11 NOV 2020 based on the start date of the initial AE. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:08:37
User closed query 'Please reconcile and enter all missing dates since 16Nov2020. As a reminder symptom log is to be updated within 24 hrs of daily illness call.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:08:37
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:10

FDA-CBER-2022-1614-6155644

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
Date

Audit	User	Time (GMT)
Query 'Please reconcile and enter all missing dates since 16Nov2020. As a reminder symptom log is to be updated within 24 hrs of daily illness call.' answered with 'Subject is in the hospital and we are unable to complete the symptom log at this time ' (Site from CRA).	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:56:32
User opened query 'Please reconcile and enter all missing dates since 16Nov2020. As a reminder symptom log is to be updated within 24 hrs of daily illness call.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:54:27
User entered '16 Nov 2020'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155645

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
Assessment Not Done

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered '0'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155646

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
O2 Saturation

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered '86'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155647

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155648

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
Temperature

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered '98.7' F	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155649

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
Chills

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155650

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
Cough

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155651

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
Shortness of Breath

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155652

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
Difficulty Breathing

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155653

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
Fatigue

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155654

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155655

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
Body Aches

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155656

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
Headache

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155657

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
New Loss of Taste

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155658

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
New Loss of Smell

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155659

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
Nasal Congestion

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155660

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155661

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
Nausea

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155662

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
Vomiting

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155663

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
Diarrhea

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155664

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:11:02
Sore Throat

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

FDA-CBER-2022-1614-6155665

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155666

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered '11 Nov 2020'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155667

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
Assessment Not Done

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered '0'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155668

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
O2 Saturation

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered missing code ND - Not Done.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155669

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155670

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
Temperature

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered missing code ND - Not Done.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155671

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
Chills

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155672

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
Cough

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155673

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
Shortness of Breath

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155674

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
Difficulty Breathing

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155675

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
Fatigue

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155676

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155677

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
Body Aches

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155678

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
Headache

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155679

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
New Loss of Taste

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155680

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
New Loss of Smell

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155681

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
Nasal Congestion

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155682

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155683

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
Nausea

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155684

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
Vomiting

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155685

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
Diarrhea

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155686

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:11:02
Sore Throat

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

FDA-CBER-2022-1614-6155687

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155688

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered '12 Nov 2020'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155689

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
Assessment Not Done

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered '0'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155690

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
O2 Saturation

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered missing code ND - Not Done.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155691

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155692

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
Temperature

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered missing code ND - Not Done.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155693

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
Chills

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155694

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
Cough

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155695

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
Shortness of Breath

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155696

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
Difficulty Breathing

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155697

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
Fatigue

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155698

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155699

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
Body Aches

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155700

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
Headache

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155701

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
New Loss of Taste

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155702

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
New Loss of Smell

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155703

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
Nasal Congestion

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155704

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155705

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
Nausea

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155706

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
Vomiting

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155707

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
Diarrhea

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155708

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:11:02
Sore Throat

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

FDA-CBER-2022-1614-6155709

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155710

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered '13 Nov 2020'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155711

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
Assessment Not Done

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered '0'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155712

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
O2 Saturation

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered missing code ND - Not Done.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155713

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155714

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
Temperature

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered missing code ND - Not Done.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155715

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
Chills

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155716

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
Cough

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155717

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
Shortness of Breath

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155718

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
Difficulty Breathing

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155719

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
Fatigue

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155720

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155721

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
Body Aches

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155722

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
Headache

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155723

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
New Loss of Taste

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155724

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
New Loss of Smell

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155725

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
Nasal Congestion

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155726

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155727

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
Nausea

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155728

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
Vomiting

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155729

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
Diarrhea

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155730

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:11:02
Sore Throat

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

FDA-CBER-2022-1614-6155731

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155732

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered '14 Nov 2020'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155733

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
Assessment Not Done

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered '0'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155734

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
O2 Saturation

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered missing code ND - Not Done.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155735

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155736

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
Temperature

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered missing code ND - Not Done.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155737

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
Chills

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155738

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
Cough

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155739

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
Shortness of Breath

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155740

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
Difficulty Breathing

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155741

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
Fatigue

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155742

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155743

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
Body Aches

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155744

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
Headache

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155745

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
New Loss of Taste

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155746

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
New Loss of Smell

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155747

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
Nasal Congestion

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155748

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155749

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
Nausea

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155750

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
Vomiting

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155751

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
Diarrhea

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155752

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:11:02
Sore Throat

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

FDA-CBER-2022-1614-6155753

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155754

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered '15 Nov 2020'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155755

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
Assessment Not Done

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered '0'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155756

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
O2 Saturation

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered missing code ND - Not Done.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155757

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155758

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
Temperature

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered missing code ND - Not Done.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155759

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
Chills

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155760

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
Cough

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155761

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
Shortness of Breath

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155762

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
Difficulty Breathing

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155763

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
Fatigue

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155764

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155765

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
Body Aches

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155766

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
Headache

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155767

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
New Loss of Taste

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155768

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
New Loss of Smell

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155769

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
Nasal Congestion

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155770

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155771

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
Nausea

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155772

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
Vomiting

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155773

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
Diarrhea

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155774

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:11:02
Sore Throat

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

FDA-CBER-2022-1614-6155775

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:11:02
Date of Visit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:33:44
User entered '16 Nov 2020'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:26

FDA-CBER-2022-1614-6155776

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:11:02
Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:33:44
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:26

FDA-CBER-2022-1614-6155777

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:11:02
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:33:44
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 14:56:45
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Updated' (Site from System).	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:44
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	18 Nov 2020 19:48:26
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:26

FDA-CBER-2022-1614-6155778

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:11:02
Date of Test

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:33:44
User entered '16 Nov 2020'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:26

FDA-CBER-2022-1614-6155779

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:11:02
Type of Test Performed

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:33:44
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:26

FDA-CBER-2022-1614-6155780

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:11:02
Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:33:44
User entered empty.	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:26

FDA-CBER-2022-1614-6155781

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:11:02

Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:33:44
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:26

FDA-CBER-2022-1614-6155782

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:11:02
Lab/ Institution Test Performed

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:33:44
User entered empty.	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:26

FDA-CBER-2022-1614-6155783

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:11:02
CLIA Certified?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:33:44
User entered empty.	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:26

FDA-CBER-2022-1614-6155784

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:11:02
COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 19:48:26

FDA-CBER-2022-1614-6155785

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155786

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155787

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155788

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Respiratory Rate

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155789

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Did the subject have Heart Rate ≥ 125 beats per minute

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155790

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155791

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155792

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Heart Rate

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155793

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155794

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered '16 Nov 2020'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155795

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered '16 Nov 2020'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155796

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Oxygen Saturation

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered '86'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155797

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155798

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155799

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155800

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
PaO2

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155801

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Did the subject have Respiratory failure?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155802

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155803

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155804

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155805

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
High-Flow Oxygen?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155806

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155807

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155808

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Non-Invasive Ventilation?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155809

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155810

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155811

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Mechanical Ventilation?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155812

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155813

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155814

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
ECMO?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155815

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155816

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155817

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155818

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155819

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155820

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Evidence of Shock Requires Vasopressors

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155821

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155822

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155823

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Acute Renal Dysfunction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155824

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155825

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Hepatic Dysfunction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155826

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155827

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Neurologic Dysfunction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155828

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155829

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Clinical Evidence

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155830

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Date of Assessment

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered '16 Nov 2020'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155831

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Radiographical Evidence

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155832

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Date of Assessment

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered '16 Nov 2020'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155833

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Admission to an intensive care unit due to SARS-CoV-2

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155834

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155835

US3722066
Folder: Covid-19 Assessment 16 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:11:02
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

FDA-CBER-2022-1614-6155836

US3722066
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02
Was this visit performed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:11
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:49:47

FDA-CBER-2022-1614-6155837

US3722066
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:11
User entered '16 Nov 2020'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:49:47

FDA-CBER-2022-1614-6155838

US3722066
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:11
User entered 'Clinic (Clinic)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:49:47

FDA-CBER-2022-1614-6155839

US3722066
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:11:02
Folder OID

Audit	User	Time (GMT)
User entered 'SICKD1'	System	18 Nov 2020 19:49:47

FDA-CBER-2022-1614-6155840

US3722066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Were vital signs assessed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:15

FDA-CBER-2022-1614-6155841

US3722066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered '16 Nov 2020'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:15

FDA-CBER-2022-1614-6155842

US3722066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:08:26
User closed query 'Please verify time of assessment, as source indicates 15:20.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 02:08:24
Query 'Please verify time of assessment, as source indicates 15:20.' answered with 'Updated' (Site from CRA).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:40:50
User entered '15:20' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:40:42
User opened query 'Please verify time of assessment, as source indicates 15:20.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:41:25
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 20:40:55
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered '15:26'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:15

FDA-CBER-2022-1614-6155843

US3722066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '16 Nov 2020 15:20'	System	24 Nov 2020 00:40:42
User entered '16 Nov 2020 15:26'	System	18 Nov 2020 20:01:15

FDA-CBER-2022-1614-6155844

US3722066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Height *(xxx.x)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered '167' cm	Sara Poff (b) (4)	18 Nov 2020 20:01:15
DataPoint set to visible.	(b) (4) System	18 Nov 2020 19:49:47

FDA-CBER-2022-1614-6155845

US3722066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Weight *(xxx.x)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered '196' lb	Sara Poff (b) (4)	18 Nov 2020 20:01:15
DataPoint set to visible.	System	18 Nov 2020 19:49:47

FDA-CBER-2022-1614-6155846

US3722066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Temperature *(xxx.x)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered '98.7' F	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:15

FDA-CBER-2022-1614-6155847

US3722066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Route of measurement

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered 'Oral (Oral)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:15

FDA-CBER-2022-1614-6155848

US3722066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
If Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered empty.	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:15

FDA-CBER-2022-1614-6155849

US3722066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Pulse *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered '81'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:15

FDA-CBER-2022-1614-6155850

US3722066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Nov 2020 20:01:15

FDA-CBER-2022-1614-6155851

US3722066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered '24'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:15

FDA-CBER-2022-1614-6155852

US3722066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Nov 2020 20:01:15

FDA-CBER-2022-1614-6155853

US3722066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered '155'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:15

FDA-CBER-2022-1614-6155854

US3722066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Nov 2020 20:01:15

FDA-CBER-2022-1614-6155855

US3722066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered '83'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:15

FDA-CBER-2022-1614-6155856

US3722066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:11:02
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Nov 2020 20:01:15

FDA-CBER-2022-1614-6155857

US3722066
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:11:02
Was the physical examination performed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:41:58
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:40

FDA-CBER-2022-1614-6155858

US3722066
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:11:02
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:41:58
User entered '16 Nov 2020'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:40

FDA-CBER-2022-1614-6155859

US3722066
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 26 Nov 2020 11:11:02
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:42:05
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:49

FDA-CBER-2022-1614-6155860

US3722066
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 26 Nov 2020 11:11:02
Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:42:05
User entered '16 Nov 2020'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:49

FDA-CBER-2022-1614-6155861

US3722066
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 26 Nov 2020 11:11:02
Did the participant experience any adverse events?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:41
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 19:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:20:20
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:11:58

FDA-CBER-2022-1614-6155862

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
AEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:08:48
User entered 'USA-US083-2020-mRNA-1273-P301000007'	System	18 Nov 2020 18:08:44
User entered 'New'	(b) (4), (b) (6)	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6155863

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'PV Query Urgent: Please confirm - is reported events of a single occurrence or recurrence? If single, please report only 1 event of COVID 19 positive. Please consider merging non-serious and serious details in 1 log line. Please consider deleting the other. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 16:02:38
Query 'PV Query Urgent: Please confirm - is reported events of a single occurrence or recurrence? If single, please report only 1 event of COVID 19 positive. Please consider merging non-serious and serious details in 1 log line. Please consider deleting the other. ' answered with 'Due to the seriousness of the situation, the AE and SAE have been made separate. ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	19 Nov 2020 15:13:35
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 13:38:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 13:38:59
Data point term sent to Coder	System	19 Nov 2020 13:38:21
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Positive COVID 19' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55
Data point term sent to Coder	System	19 Nov 2020 13:33:15
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:09
User opened query 'PV Query Urgent: Please confirm - is reported events of a single occurrence or recurrence? If single, please report only 1 event of COVID 19 positive. Please consider merging non-serious and serious details in 1 log line. Please consider deleting the other. ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 02:11:36

FDA-CBER-2022-1614-6155864

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Adverse event

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: COVID-19 virus test positive - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 20:19:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 20:19:50
Data point term sent to Coder	System	17 Nov 2020 20:18:53
User entered 'COVID-19 Positive'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:09
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155866

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:36:17
User closed query 'Thank you for your previous response however this event would not be consider a solicited adverse reaction as ARs are only evaluated during the 7 day period after dosing. Please consider revising the response else clarify.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 02:36:15
User entered 'No (N)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	24 Nov 2020 02:26:57
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
Query 'Thank you for your previous response however this event would not be consider a solicited adverse reaction as ARs are only evaluated during the 7 day period after dosing. Please consider revising the response else clarify.' answered with 'Subject has been hospitalized due to COVID 19. ' (Site from CRA).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:32:08
User opened query 'Thank you for your previous response however this event would not be consider a solicited adverse reaction as ARs are only evaluated during the 7 day period after dosing. Please consider revising the response else clarify.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:07:15
Query 'Thank you for your previous response however this event would not be consider a solicited adverse reaction as ARs are only evaluated during the 7 day period after dosing.' canceled (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:06:39
User opened query 'Thank you for your previous response however this event would not be consider a solicited adverse reaction as ARs are only evaluated during the 7 day period after dosing.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:06:24
User closed query 'Please reconcile as this was outside of AR reporting for 7 days post dosing.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:06:24
Query 'Please reconcile as this was outside of AR reporting for 7 days post dosing.' answered with 'This is a SAE that was reported as directed ' (Site from CRA).	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:52:03

FDA-CBER-2022-1614-6155867

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User opened query 'Please reconcile as this was outside of AR reporting for 7 days post dosing.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:56:00
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:09
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155868

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:09
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Un-verified.	Sara Poff (b) (4) (b) (4)	25 Nov 2020 03:42:45
User entered '11 Nov 2020' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	25 Nov 2020 03:42:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered '16 Nov 2020' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:09
User entered '16 Nov 2020'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155870

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	17 Nov 2020 20:30:44
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:30:44
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	17 Nov 2020 20:18:07
User entered '15:30'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155871

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 20:30:44
User entered '16 Nov 2020 15:30'	System	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155872

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:09
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155873

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'The subject is still in the hospital ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 21:03:52
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:27:59
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered empty.	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155874

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered empty.	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155875

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155876

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:09
User entered 'Grade 3/Severe (Grade 3/Severe)'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155877

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:09
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155878

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered '0'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155879

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered '0'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155880

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
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)	19 Nov 2020 19:08:37
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 'This has been updated upon speaking to the subject. ' (Site from System).	Sara Poff (b) (4) (b) (4)	19 Nov 2020 15:12:44
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	19 Nov 2020 15:12:12
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)	19 Nov 2020 14:53:01
User entered '1' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55
User entered '0' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:43
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 'updated' (Site from System).	Marlee Smith (b) (4) (b) (4)	18 Nov 2020 18:42:49
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	17 Nov 2020 20:18:07
User entered '1'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155881

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'PV Query: Please confirm the hospital admission date, it was reported as 16 Nov 2020 and 17 Nov 2020.' answered with 'Admission date is 16 NOV 2020' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 21:04:23
User opened query 'PV Query: Please confirm the hospital admission date, it was reported as 16 Nov 2020 and 17 Nov 2020.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:28:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered '16 Nov 2020' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:09
User entered '17 Nov 2020'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155882

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Subject is still in the hospital ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 21:06:22
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:27:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered empty.	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	19 Nov 2020 15:12:12
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	19 Nov 2020 15:12:12
User entered 'No (N)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 15:12:12
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Unknown (UNK)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	19 Nov 2020 13:33:09
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:09
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	17 Nov 2020 20:18:07
User entered 'Unknown (UNK)'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155884

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered empty.	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155885

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered '0'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155886

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered '0'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155887

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered '0'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155888

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:09
User entered 'Not Related (NOT RELATED)'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155889

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:09
User entered 'Not Related (NOT RELATED)'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155890

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Action taken with investigational product

Audit	User	Time (GMT)
Query 'PV Query: As the last dose of was given on 28 Aug 2020, please consider updating the action taken from none to not applicable.' answered with 'Updated and completed ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 21:06:58
DataPoint Un-verified.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 21:06:44
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	24 Nov 2020 21:06:44
User opened query 'PV Query: As the last dose of was given on 28 Aug 2020, please consider updating the action taken from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:27:19
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered 'None (NONE)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:09
User entered 'None (NONE)'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155891

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Nov 2020 13:37:55
User entered '1' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Nov 2020 13:33:09
User entered '0' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:09
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	17 Nov 2020 20:30:44
User entered '1' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:30:44
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	17 Nov 2020 20:18:07
User entered '0'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155892

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered '0'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155893

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered '0'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155894

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Outcome

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:28:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:09
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155895

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered empty.	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155896

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please consider reporting only one event of Covid-19 and merging the non-serious and serious events into one event.' answered with 'Completed' (Site from Safety).	Sara Poff (b) (4) (b) (4)	25 Nov 2020 03:42:59
Query 'PV Query: Please complete Covid-19 Assessment symptom log, starting on 11 Nov 2020 when it was reported that symptoms started.' answered with 'Completed ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 21:20:34
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Subject is still in hospital, will request medical records upon release ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 21:08:49
Query 'V 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 'Subject is still in hospital, will request medical records upon release ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 21:08:29
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Subject is still in hospital, will request medical records upon release ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 21:08:20
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 'Subject is still in hospital, will request medical records upon release ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 21:08:16

FDA-CBER-2022-1614-6155897

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:29:06
User opened query 'PV Query: Please complete Covid-19 Assessment symptom log, starting on 11 Nov 2020 when it was reported that symptoms started.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:28:41
User opened query 'PV Query: Please consider reporting only one event of Covid-19 and merging the non-serious and serious events into one event.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:28:32
User opened query 'V 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)	24 Nov 2020 19:28:24
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)	24 Nov 2020 19:27:30
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)	24 Nov 2020 19:27:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Nov 2020 13:38:21
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	19 Nov 2020 13:38:21

FDA-CBER-2022-1614-6155898

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Narrative

Audit	User	Time (GMT)
User entered 'SITE RECEIVED AN EMAIL ALERT ON 15NOV2020, STATING THAT THE SUBJECT HAD COVID 19 SYMPTOMS. SUBJECT WAS CALLED ON 16NOV2020 AT 08:49 AND AT THAT TIME HE STATED THEY HAD SOB, FEVER OF UP TO 102.6, CHILLS, AND MUSCLE ACHES. SUBJECT WAS ADVISED TO GO TO ER IN THE EVENT OF AN EMERGENCY. SUBJECT EXPRESSED HE JUST THOUGHT HE HAD PNEUMONIA. PER PROTOCOL, SUBJECT WAS SCHEDULED TO COME TO SITE FOR A CONVALESCENT VISIT. UPON ARRIVING THE SUBJECT STATED THAT THEY HAD RECEIVED THEIR TEST RESULTS BACK AND THAT THEY HAD TESTED POSITIVE FOR COVID 19. HIS O2 WAS 87% AT TIME OF VISIT AND THIS WAS CONFIRMED WITH A SECOND READING. THE SUB I ONSITE CONTACTED THE PI WHO ADVISED EMS TO BE CALLED FOR PATIENT TO GO TO THE ER. AT THAT TIME 911 WAS CALLED AND THE SUBJECT WAS TRANSPORTED TO THE ER. SUBJECT WAS TAKEN TO ST. FRANCES DOWNTOWN PER SUBJECT REQUEST. SITE WILL CONTINUE TO FOLLOW UP WITH SUBJECT AS REQUIRED PER PROTOCOL. SUBJECT CONFIRMED VIA PHONE HE WAS ADMITTED TO HOSPITAL ON 17 NOV 2020. SAE DOCUMENTED IN SOURCE AND SPONSOR NOTIFIED. SITE WILL CONTINUE TO FOLLOW PROGRESS OF PATIENT AND WILL GET A MEDICAL RECORDS RELEASE AS SOON AS POSSIBLE IN ORDER TO GET RECORDS.' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:38:21
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Nov 2020 13:37:55
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:09

FDA-CBER-2022-1614-6155899

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Narrative

Audit	User	Time (GMT)
User entered 'Site received an email alert on 15NOV2020, stating that the subject had COVID 19 symptoms. Subject was called on 16NOV2020 at 08:49 and at that time he stated they had SOB, fever of up to 102.6, chills, and muscle aches. Subject was advised to go to ER in the event of an emergency. Subject expressed he just thought he had pneumonia. Per protocol, subject was scheduled to come to site for a convalescent visit. Upon arriving the subject stated that they had received their test results back and that they had tested positive for COVID 19. His O2 was 87% at time of visit and this was confirmed with a second reading. The Sub I onsite contacted the PI who advised EMS to be called for patient to go to the ER. At that time 911 was called and the subject was transported to the ER. Subject was taken to St. Frances Downtown per subject request. Site will continue to follow up with subject as required per protocol. Subject confirmed via phone he was admitted to hospital on 17 NOV 2020. SAE documented in source and sponsor notified. Site will continue to follow progress of patient and will get a medical records release as soon as possible in order to get records.'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155900

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155901

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155902

US3722066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:11:02
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	17 Nov 2020 20:18:07

FDA-CBER-2022-1614-6155903

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:11:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:39:27
User closed query 'Per CDM : In Diary Dose 1 - Temperature Day 11,12,13,14,15 & 16 , Medication was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:32:09
Query 'Per CDM : In Diary Dose 1 - Temperature Day 11,12,13,14,15 & 16 , Medication was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' answered with 'According to source, subject was taking Tylenol for arthritis and not for vaccine. Conmed was added to conmeds as such. Arthritis is in MH ' (Site from DM).	Sara Poff (b) (4) (b) (4)	22 Oct 2020 22:28:26
User opened query 'Per CDM : In Diary Dose 1 - Temperature Day 11,12,13,14,15 & 16 , Medication was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 06:40:33
Query 'Per CDM : In Diary Dose 1 - Temperature Day 12,13,14,15 & 16 , Medication was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' canceled (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 06:40:18
User opened query 'Per CDM : In Diary Dose 1 - Temperature Day 12,13,14,15 & 16 , Medication was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 13:22:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:02:12
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:00:00

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:11:02
Name of Medication

Audit	User	Time (GMT)
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 BESILATE, PRODUCTSYNONYM: AMLODIPINE BESYLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:26:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:26:13
Data point term sent to Coder	System	12 Aug 2020 20:25:20
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:24:40
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 BESILATE, PRODUCTSYNONYM: AMLODIPINE BESYLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:04:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:04:09
Data point term sent to Coder	System	11 Aug 2020 15:03:06
User entered 'amlodipine besylate'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

FDA-CBER-2022-1614-6155905

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:11:02
Prophylaxis

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

FDA-CBER-2022-1614-6155906

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:11:02
Indication

Audit	User	Time (GMT)
User closed query 'Per CDM : In Diary Dose 1 - Temperature Day 11, Medication was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 06:39:00
Query 'Per CDM : In Diary Dose 1 - Temperature Day 11, Medication was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' answered with 'SUBJECT ALREADY TAKING TYLENOL FOR MEDICAL HISTORY OF ARTHRITIS. NOT TAKEN FOR SOLICITED REACTION OF INJECTION' (Site from DM).	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:23:20
User opened query 'Per CDM : In Diary Dose 1 - Temperature Day 11, Medication was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 12:19:03
User entered 'hypertension' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:24:40
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

FDA-CBER-2022-1614-6155907

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:11:02
Dose per administration

Audit	User	Time (GMT)
User entered '10'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

FDA-CBER-2022-1614-6155908

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:11:02
Dose unit

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

FDA-CBER-2022-1614-6155909

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:11:02
If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

FDA-CBER-2022-1614-6155910

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:11:02
Frequency

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

FDA-CBER-2022-1614-6155911

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:11:02
If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

FDA-CBER-2022-1614-6155912

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:11:02
Route of administration

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

FDA-CBER-2022-1614-6155913

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:11:02
If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

FDA-CBER-2022-1614-6155914

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:11:02
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:38:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 15:03:02
User entered 'un UNK 2005'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

FDA-CBER-2022-1614-6155915

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

FDA-CBER-2022-1614-6155916

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:11:02
Ongoing?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

FDA-CBER-2022-1614-6155917

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:11:02
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

FDA-CBER-2022-1614-6155918

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:11:02
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

FDA-CBER-2022-1614-6155919

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:11:02
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:03:02

FDA-CBER-2022-1614-6155920

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:03:02

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:03:02

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:11:02
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:26:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:26:14
Data point term sent to Coder	System	12 Aug 2020 20:25:20
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:24:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:09:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:09:13
Data point term sent to Coder	System	11 Aug 2020 15:04:08
User entered 'atorvastain'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

FDA-CBER-2022-1614-6155923

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:11:02
Prophylaxis

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

FDA-CBER-2022-1614-6155924

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:11:02
Indication

Audit	User	Time (GMT)
User entered 'hypercholesterolemia' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:24:56
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

FDA-CBER-2022-1614-6155925

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:11:02
Dose per administration

Audit	User	Time (GMT)
User entered '20'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

FDA-CBER-2022-1614-6155926

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:11:02
Dose unit

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

FDA-CBER-2022-1614-6155927

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:11:02
If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

FDA-CBER-2022-1614-6155928

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:11:02
Frequency

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

FDA-CBER-2022-1614-6155929

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:11:02
If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

FDA-CBER-2022-1614-6155930

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:11:02
Route of administration

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

FDA-CBER-2022-1614-6155931

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:11:02
If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

FDA-CBER-2022-1614-6155932

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:11:02
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:38:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 15:03:45
User entered 'un UNK 1990'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

FDA-CBER-2022-1614-6155933

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

FDA-CBER-2022-1614-6155934

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:11:02
Ongoing?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

FDA-CBER-2022-1614-6155935

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:11:02
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

FDA-CBER-2022-1614-6155936

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:11:02
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

FDA-CBER-2022-1614-6155937

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:11:02
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:03:45

FDA-CBER-2022-1614-6155938

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:03:45

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:03:45

FDA-CBER-2022-1614-6155940

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:11:02
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:26:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:26:13
Data point term sent to Coder	System	12 Aug 2020 20:25:21
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:25:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:06:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:06:11
Data point term sent to Coder	System	11 Aug 2020 15:05:09
User entered 'gabapentin'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

FDA-CBER-2022-1614-6155941

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:11:02
Prophylaxis

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

FDA-CBER-2022-1614-6155942

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:11:02
Indication

Audit	User	Time (GMT)
User entered 'restless leg syndrome' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:25:08
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

FDA-CBER-2022-1614-6155943

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:11:02
Dose per administration

Audit	User	Time (GMT)
User entered '1500'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

FDA-CBER-2022-1614-6155944

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:11:02
Dose unit

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

FDA-CBER-2022-1614-6155945

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:11:02
If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

FDA-CBER-2022-1614-6155946

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:11:02
Frequency

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

FDA-CBER-2022-1614-6155947

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:11:02
If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

FDA-CBER-2022-1614-6155948

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:11:02
Route of administration

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

FDA-CBER-2022-1614-6155949

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:11:02
If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

FDA-CBER-2022-1614-6155950

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:11:02
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:38:58
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 15:04:32
User entered 'un Jul 2016'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

FDA-CBER-2022-1614-6155951

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

FDA-CBER-2022-1614-6155952

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:11:02
Ongoing?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

FDA-CBER-2022-1614-6155953

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:11:02
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

FDA-CBER-2022-1614-6155954

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:11:02
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

FDA-CBER-2022-1614-6155955

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:11:02
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:04:32

FDA-CBER-2022-1614-6155956

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:04:32

FDA-CBER-2022-1614-6155957

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:04:32

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 11:11:02
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, EXCL. THIAZIDES, ATC: SULFONAMIDES, PLAIN, PRODUCT: INDAPAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 13:57:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 13:57:18
Data point term sent to Coder	System	12 Aug 2020 20:25:20
Data point term sent to Coder	System	11 Aug 2020 15:06:14
User entered 'indapamide'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

FDA-CBER-2022-1614-6155959

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 11:11:02
Prophylaxis

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

FDA-CBER-2022-1614-6155960

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 11:11:02
Indication

Audit	User	Time (GMT)
User entered 'hypertension' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:25:17
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

FDA-CBER-2022-1614-6155961

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 11:11:02
Dose per administration

Audit	User	Time (GMT)
User entered '1.25'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

FDA-CBER-2022-1614-6155962

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 11:11:02
Dose unit

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

FDA-CBER-2022-1614-6155963

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 11:11:02
If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

FDA-CBER-2022-1614-6155964

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 11:11:02
Frequency

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

FDA-CBER-2022-1614-6155965

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 11:11:02
If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

FDA-CBER-2022-1614-6155966

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 11:11:02
Route of administration

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

FDA-CBER-2022-1614-6155967

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 11:11:02
If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

FDA-CBER-2022-1614-6155968

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 11:11:02
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:39:03
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 15:05:31
User entered 'un UNK 2019'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

FDA-CBER-2022-1614-6155969

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

FDA-CBER-2022-1614-6155970

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 11:11:02
Ongoing?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

FDA-CBER-2022-1614-6155971

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 11:11:02
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

FDA-CBER-2022-1614-6155972

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 11:11:02
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

FDA-CBER-2022-1614-6155973

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 11:11:02
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:05:31

FDA-CBER-2022-1614-6155974

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:05:31

FDA-CBER-2022-1614-6155975

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:05:31

FDA-CBER-2022-1614-6155976

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 11:11:02
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:27:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:27:10
Data point term sent to Coder	System	12 Aug 2020 20:26:24
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:25:30
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:08:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:08:09
Data point term sent to Coder	System	11 Aug 2020 15:07:16
User entered 'levothyroxine'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

FDA-CBER-2022-1614-6155977

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 11:11:02
Prophylaxis

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

FDA-CBER-2022-1614-6155978

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 11:11:02
Indication

Audit	User	Time (GMT)
User entered 'hypothyroidism' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:25:30
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

FDA-CBER-2022-1614-6155979

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 11:11:02
Dose per administration

Audit	User	Time (GMT)
User entered '.112'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

FDA-CBER-2022-1614-6155980

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 11:11:02
Dose unit

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

FDA-CBER-2022-1614-6155981

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 11:11:02
If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

FDA-CBER-2022-1614-6155982

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 11:11:02
Frequency

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

FDA-CBER-2022-1614-6155983

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 11:11:02
If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

FDA-CBER-2022-1614-6155984

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 11:11:02
Route of administration

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

FDA-CBER-2022-1614-6155985

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 11:11:02
If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

FDA-CBER-2022-1614-6155986

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 11:11:02
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:39:07
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 15:06:16
User entered 'un UNK 1990'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

FDA-CBER-2022-1614-6155987

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

FDA-CBER-2022-1614-6155988

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 11:11:02
Ongoing?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

FDA-CBER-2022-1614-6155989

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 11:11:02
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

FDA-CBER-2022-1614-6155990

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 11:11:02
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

FDA-CBER-2022-1614-6155991

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 11:11:02
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:06:16

FDA-CBER-2022-1614-6155992

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:06:16

FDA-CBER-2022-1614-6155993

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:06:16

FDA-CBER-2022-1614-6155994

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 11:11:02
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:27:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:27:10
Data point term sent to Coder	System	12 Aug 2020 20:26:22
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:25:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:13:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:13:07
Data point term sent to Coder	System	11 Aug 2020 15:08:22
User entered 'omeprazole'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

FDA-CBER-2022-1614-6155995

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 11:11:02
Prophylaxis

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:28:11
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

FDA-CBER-2022-1614-6155996

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 11:11:02
Indication

Audit	User	Time (GMT)
User entered 'GERD' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:25:39
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

FDA-CBER-2022-1614-6155997

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 11:11:02
Dose per administration

Audit	User	Time (GMT)
User entered '20'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

FDA-CBER-2022-1614-6155998

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 11:11:02
Dose unit

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

FDA-CBER-2022-1614-6155999

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 11:11:02
If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

FDA-CBER-2022-1614-6156000

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 11:11:02
Frequency

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

FDA-CBER-2022-1614-6156001

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 11:11:02
If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

FDA-CBER-2022-1614-6156002

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 11:11:02
Route of administration

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

FDA-CBER-2022-1614-6156003

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 11:11:02
If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

FDA-CBER-2022-1614-6156004

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 11:11:02
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:39:11
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 15:07:36
User entered 'un UNK 1990'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

FDA-CBER-2022-1614-6156005

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

FDA-CBER-2022-1614-6156006

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 11:11:02
Ongoing?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

FDA-CBER-2022-1614-6156007

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 11:11:02
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

FDA-CBER-2022-1614-6156008

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 11:11:02
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

FDA-CBER-2022-1614-6156009

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 11:11:02
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:07:36

FDA-CBER-2022-1614-6156010

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:07:36

FDA-CBER-2022-1614-6156011

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:07:36

FDA-CBER-2022-1614-6156012

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 11:11:02
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: ROPINIROLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:27:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:27:10
Data point term sent to Coder	System	12 Aug 2020 20:26:21
Data point term sent to Coder	System	11 Aug 2020 15:08:23
User entered 'ropinirole'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

FDA-CBER-2022-1614-6156013

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 11:11:02
Prophylaxis

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

FDA-CBER-2022-1614-6156014

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 11:11:02
Indication

Audit	User	Time (GMT)
User entered 'Restless leg syndrome' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:25:53
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

FDA-CBER-2022-1614-6156015

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 11:11:02
Dose per administration

Audit	User	Time (GMT)
User entered '2'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

FDA-CBER-2022-1614-6156016

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 11:11:02
Dose unit

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

FDA-CBER-2022-1614-6156017

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 11:11:02
If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

FDA-CBER-2022-1614-6156018

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 11:11:02
Frequency

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

FDA-CBER-2022-1614-6156019

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 11:11:02
If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

FDA-CBER-2022-1614-6156020

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 11:11:02
Route of administration

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

FDA-CBER-2022-1614-6156021

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 11:11:02
If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

FDA-CBER-2022-1614-6156022

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 11:11:02
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:40:11
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 15:08:17
User entered 'un UNK 2015'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

FDA-CBER-2022-1614-6156023

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

FDA-CBER-2022-1614-6156024

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 11:11:02
Ongoing?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

FDA-CBER-2022-1614-6156025

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 11:11:02
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

FDA-CBER-2022-1614-6156026

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 11:11:02
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

FDA-CBER-2022-1614-6156027

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 11:11:02
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 15:08:17

FDA-CBER-2022-1614-6156028

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:08:17

FDA-CBER-2022-1614-6156029

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:08:17

FDA-CBER-2022-1614-6156030

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 11:11:02
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: VALSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:27:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:27:10
Data point term sent to Coder	System	12 Aug 2020 20:26:22
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:26:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: VALSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:59:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:59:07
Data point term sent to Coder	System	11 Aug 2020 15:09:28
User entered 'valsartan'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

FDA-CBER-2022-1614-6156031

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 11:11:02
Prophylaxis

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

FDA-CBER-2022-1614-6156032

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 11:11:02
Indication

Audit	User	Time (GMT)
User entered 'hypertension' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:26:04
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

FDA-CBER-2022-1614-6156033

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 11:11:02
Dose per administration

Audit	User	Time (GMT)
User entered '320'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

FDA-CBER-2022-1614-6156034

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 11:11:02
Dose unit

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

FDA-CBER-2022-1614-6156035

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 11:11:02
If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

FDA-CBER-2022-1614-6156036

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 11:11:02
Frequency

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

FDA-CBER-2022-1614-6156037

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 11:11:02
If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

FDA-CBER-2022-1614-6156038

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 11:11:02
Route of administration

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

FDA-CBER-2022-1614-6156039

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 11:11:02
If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

FDA-CBER-2022-1614-6156040

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 11:11:02
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:40:16
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 15:08:57
User entered 'un UNK 2016'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

FDA-CBER-2022-1614-6156041

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

FDA-CBER-2022-1614-6156042

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 11:11:02
Ongoing?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

FDA-CBER-2022-1614-6156043

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 11:11:02
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

FDA-CBER-2022-1614-6156044

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 11:11:02
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

FDA-CBER-2022-1614-6156045

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 11:11:02
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:08:57

FDA-CBER-2022-1614-6156046

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:08:57

FDA-CBER-2022-1614-6156047

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:08:57

FDA-CBER-2022-1614-6156048

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 11:11:02
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLOVENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:42:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:42:17
Data point term sent to Coder	System	12 Aug 2020 20:26:25
Data point term sent to Coder	System	11 Aug 2020 15:10:31
User entered 'Flovent'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

FDA-CBER-2022-1614-6156049

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 11:11:02
Prophylaxis

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

FDA-CBER-2022-1614-6156050

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 11:11:02
Indication

Audit	User	Time (GMT)
User entered 'asthma' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:26:22
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

FDA-CBER-2022-1614-6156051

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 11:11:02
Dose per administration

Audit	User	Time (GMT)
User entered '100'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

FDA-CBER-2022-1614-6156052

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 11:11:02
Dose unit

Audit	User	Time (GMT)
User entered 'ug (ug)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

FDA-CBER-2022-1614-6156053

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 11:11:02
If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

FDA-CBER-2022-1614-6156054

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 11:11:02
Frequency

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

FDA-CBER-2022-1614-6156055

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 11:11:02
If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

FDA-CBER-2022-1614-6156056

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 11:11:02
Route of administration

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

FDA-CBER-2022-1614-6156057

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 11:11:02
If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

FDA-CBER-2022-1614-6156058

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 11:11:02
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:40:20
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 15:09:38
User entered 'un UNK 1990'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

FDA-CBER-2022-1614-6156059

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

FDA-CBER-2022-1614-6156060

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 11:11:02
Ongoing?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

FDA-CBER-2022-1614-6156061

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 11:11:02
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

FDA-CBER-2022-1614-6156062

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 11:11:02
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

FDA-CBER-2022-1614-6156063

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 11:11:02
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 15:09:38

FDA-CBER-2022-1614-6156064

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:09:38

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:09:38

FDA-CBER-2022-1614-6156066

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 11:11:02
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: IPRATROPIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:17:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:17:35
Data point term sent to Coder	System	21 Oct 2020 17:26:37
Coding entries removed.	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:25:39
User entered 'IPRATROPIUM .006%' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:25:39
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: IPRATROPIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 14:07:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 14:07:48
Data point term sent to Coder	System	25 Sep 2020 13:18:00
Coding entries removed.	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:17:59
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: IPRATROPIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 10:47:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 10:47:12
Data point term sent to Coder	System	12 Aug 2020 20:27:26
Data point term sent to Coder	System	11 Aug 2020 15:11:33
User entered 'ipratropium'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

FDA-CBER-2022-1614-6156067

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 11:11:02
Prophylaxis

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

FDA-CBER-2022-1614-6156068

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 11:11:02
Indication

Audit	User	Time (GMT)
User entered 'rhinorrhea' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:26:37
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

FDA-CBER-2022-1614-6156069

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 11:11:02
Dose per administration

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 18:24:38
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	Amy Ford (b) (4) (b) (4)	27 Oct 2020 14:58:37
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 03:25:32
User closed query 'Per DM CLR: Note 0.006% is a dose strength rather than an actual dosage. Please update the Med Name to include the dose strength (e.g. Ipratropium 0.006%) and enter the correct dosage form in the Dose & Unit fields (e.g. 1 Spray). Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 17:19:25
Query 'Per DM CLR: Note 0.006% is a dose strength rather than an actual dosage. Please update the Med Name to include the dose strength (e.g. Ipratropium 0.006%) and enter the correct dosage form in the Dose & Unit fields (e.g. 1 Spray). Update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:25:48
User entered '2' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:25:39
User opened query 'Per DM CLR: Note 0.006% is a dose strength rather than an actual dosage. Please update the Med Name to include the dose strength (e.g. Ipratropium 0.006%) and enter the correct dosage form in the Dose & Unit fields (e.g. 1 Spray). Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:33:53
User entered '.006'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

FDA-CBER-2022-1614-6156070

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 11:11:02
Dose unit

Audit	User	Time (GMT)
User entered 'Other (OTHER)' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	27 Oct 2020 14:58:20
User closed query 'Per DM CLR: Please review "Other Route" as there is an available option for "Nasal" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 06:41:09
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	21 Oct 2020 17:27:33
Query 'Per DM CLR: Please review "Other Route" as there is an available option for "Nasal" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' answered with 'UPDATED' (Site from DM).	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:27:08
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 17:27:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 17:27:00
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	21 Oct 2020 17:27:00
User entered 'ug (ug)' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:27:00
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 17:26:45
User entered empty; reason for change Data Entry Error	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:26:45
User opened query 'Per DM CLR: Please review "Other Route" as there is an available option for "Nasal" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:34:02
User entered 'Other (OTHER)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

FDA-CBER-2022-1614-6156071

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 11:11:02
If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'sprays each nostril' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	27 Oct 2020 14:58:20
User entered empty; reason for change Data Entry Error	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:27:33
User entered 'SPRAYS EACH NOSTRIL' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:25:39
User entered 'per cent'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

FDA-CBER-2022-1614-6156072

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 11:11:02
Frequency

Audit	User	Time (GMT)
User entered 'once daily (QD)' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:25:39
User entered 'twice daily (BID)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

FDA-CBER-2022-1614-6156073

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 11:11:02
If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

FDA-CBER-2022-1614-6156074

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 11:11:02
Route of administration

Audit	User	Time (GMT)
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:17:59
User entered 'Other (OTHER)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

FDA-CBER-2022-1614-6156075

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 11:11:02
If route of administration is Other, specify

Audit	User	Time (GMT)
User closed query 'Per CDM: Please note that "Nasal" is an available option for route of administration. Kindly consider to update Route of Administration field as appropriate and remove "2 SPRAYS EACH NOSTRIL" in If route of administration is Other, specify.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 19:26:44
Query 'Per CDM: Please note that "Nasal" is an available option for route of administration. Kindly consider to update Route of Administration field as appropriate and remove "2 SPRAYS EACH NOSTRIL" in If route of administration is Other, specify.' answered with 'updated' (Site from DM).	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:18:06
User entered empty; reason for change Data Entry Error	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:17:59
User opened query 'Per CDM: Please note that "Nasal" is an available option for route of administration. Kindly consider to update Route of Administration field as appropriate and remove "2 SPRAYS EACH NOSTRIL" in If route of administration is Other, specify.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 08:45:28
User entered '2 sprays each nostril'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 11:11:02
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:40:25
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 15:11:09
User entered 'un UNK 2019'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

FDA-CBER-2022-1614-6156077

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

FDA-CBER-2022-1614-6156078

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 11:11:02
Ongoing?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

FDA-CBER-2022-1614-6156079

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 11:11:02
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

FDA-CBER-2022-1614-6156080

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 11:11:02
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

FDA-CBER-2022-1614-6156081

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 11:11:02
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:25:39
User entered '2'	System	11 Aug 2020 15:11:09

FDA-CBER-2022-1614-6156082

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:11:09

FDA-CBER-2022-1614-6156083

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:11:09

FDA-CBER-2022-1614-6156084

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 11:11:02
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:28:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:28:12
Data point term sent to Coder	System	12 Aug 2020 20:27:28
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:26:48
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:13:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:13:14
Data point term sent to Coder	System	11 Aug 2020 15:12:34
User entered 'montelukast'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

FDA-CBER-2022-1614-6156085

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 11:11:02
Prophylaxis

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

FDA-CBER-2022-1614-6156086

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 11:11:02
Indication

Audit	User	Time (GMT)
User entered 'seasonal allergies' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:26:48
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

FDA-CBER-2022-1614-6156087

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 11:11:02
Dose per administration

Audit	User	Time (GMT)
User entered '10'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

FDA-CBER-2022-1614-6156088

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 11:11:02
Dose unit

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

FDA-CBER-2022-1614-6156089

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 11:11:02
If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

FDA-CBER-2022-1614-6156090

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 11:11:02
Frequency

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

FDA-CBER-2022-1614-6156091

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 11:11:02
If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

FDA-CBER-2022-1614-6156092

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 11:11:02
Route of administration

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

FDA-CBER-2022-1614-6156093

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 11:11:02
If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

FDA-CBER-2022-1614-6156094

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 11:11:02
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:40:29
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 15:11:53
User entered 'un UNK 1990'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

FDA-CBER-2022-1614-6156095

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

FDA-CBER-2022-1614-6156096

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 11:11:02
Ongoing?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

FDA-CBER-2022-1614-6156097

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 11:11:02
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

FDA-CBER-2022-1614-6156098

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 11:11:02
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

FDA-CBER-2022-1614-6156099

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 11:11:02
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:11:53

FDA-CBER-2022-1614-6156100

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:11:53

FDA-CBER-2022-1614-6156101

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:11:53

FDA-CBER-2022-1614-6156102

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 11:11:02
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: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:28:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:28:12
Data point term sent to Coder	System	12 Aug 2020 20:27:28
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:27:04
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:15:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:15:12
Data point term sent to Coder	System	11 Aug 2020 15:13:37
User entered 'aspirin'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

FDA-CBER-2022-1614-6156103

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 11:11:02
Prophylaxis

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

FDA-CBER-2022-1614-6156104

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 11:11:02
Indication

Audit	User	Time (GMT)
User entered 'cardiac prophylaxis' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:27:04
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

FDA-CBER-2022-1614-6156105

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 11:11:02
Dose per administration

Audit	User	Time (GMT)
User entered '81'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

FDA-CBER-2022-1614-6156106

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 11:11:02
Dose unit

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

FDA-CBER-2022-1614-6156107

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 11:11:02
If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

FDA-CBER-2022-1614-6156108

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 11:11:02
Frequency

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

FDA-CBER-2022-1614-6156109

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 11:11:02
If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

FDA-CBER-2022-1614-6156110

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 11:11:02
Route of administration

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

FDA-CBER-2022-1614-6156111

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 11:11:02
If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

FDA-CBER-2022-1614-6156112

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 11:11:02
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:40:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 15:12:45
User entered 'un UNK 2010'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

FDA-CBER-2022-1614-6156113

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

FDA-CBER-2022-1614-6156114

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 11:11:02
Ongoing?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

FDA-CBER-2022-1614-6156115

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 11:11:02
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

FDA-CBER-2022-1614-6156116

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 11:11:02
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

FDA-CBER-2022-1614-6156117

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 11:11:02
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:12:45

FDA-CBER-2022-1614-6156118

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:12:45

FDA-CBER-2022-1614-6156119

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:12:45

FDA-CBER-2022-1614-6156120

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:02

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:28:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:28:12
Data point term sent to Coder	System	12 Aug 2020 20:27:28
Data point term sent to Coder	System	11 Aug 2020 15:13:39
User entered 'ferrous sulfate'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 11:11:02
Prophylaxis

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

FDA-CBER-2022-1614-6156122

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 11:11:02
Indication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 06:44:27
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'UPDATED' (Site from DM).	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:29:07
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 08:50:53
User entered 'iron deficiency anemia' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:27:22
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

FDA-CBER-2022-1614-6156123

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 11:11:02
Dose per administration

Audit	User	Time (GMT)
User entered '130'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

FDA-CBER-2022-1614-6156124

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 11:11:02
Dose unit

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

FDA-CBER-2022-1614-6156125

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 11:11:02
If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

FDA-CBER-2022-1614-6156126

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 11:11:02
Frequency

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

FDA-CBER-2022-1614-6156127

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 11:11:02
If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

FDA-CBER-2022-1614-6156128

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 11:11:02
Route of administration

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

FDA-CBER-2022-1614-6156129

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 11:11:02
If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

FDA-CBER-2022-1614-6156130

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 11:11:02
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:40:38
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 15:13:27
User entered 'un UNK 1995'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

FDA-CBER-2022-1614-6156131

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

FDA-CBER-2022-1614-6156132

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 11:11:02
Ongoing?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

FDA-CBER-2022-1614-6156133

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 11:11:02
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

FDA-CBER-2022-1614-6156134

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 11:11:02
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

FDA-CBER-2022-1614-6156135

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 11:11:02
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:13:27

FDA-CBER-2022-1614-6156136

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:13:27

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:13:27

FDA-CBER-2022-1614-6156138

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 11:11:02
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 ER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:29:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:29:14
Data point term sent to Coder	System	12 Aug 2020 20:28:29
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:27:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL ER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:17:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:17:09
Data point term sent to Coder	System	11 Aug 2020 15:15:45
User entered 'tylenol ER'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 11:11:02
Prophylaxis

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

FDA-CBER-2022-1614-6156140

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 11:11:02
Indication

Audit	User	Time (GMT)
User entered 'osteoarthritis' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:27:42
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

FDA-CBER-2022-1614-6156141

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 11:11:02
Dose per administration

Audit	User	Time (GMT)
User entered '650'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

FDA-CBER-2022-1614-6156142

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 11:11:02
Dose unit

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

FDA-CBER-2022-1614-6156143

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 11:11:02
If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

FDA-CBER-2022-1614-6156144

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 11:11:02
Frequency

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

FDA-CBER-2022-1614-6156145

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 11:11:02
If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

FDA-CBER-2022-1614-6156146

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 11:11:02
Route of administration

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

FDA-CBER-2022-1614-6156147

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 11:11:02
If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

FDA-CBER-2022-1614-6156148

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 11:11:02
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:40:42
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 15:15:01
User entered 'un UNK 2018'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

FDA-CBER-2022-1614-6156149

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

FDA-CBER-2022-1614-6156150

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 11:11:02
Ongoing?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

FDA-CBER-2022-1614-6156151

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 11:11:02
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

FDA-CBER-2022-1614-6156152

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 11:11:02
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

FDA-CBER-2022-1614-6156153

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 11:11:02
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 15:15:01

FDA-CBER-2022-1614-6156154

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:15:01

FDA-CBER-2022-1614-6156155

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:15:01

FDA-CBER-2022-1614-6156156

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 11:11:02
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: COQ10 [UBIDECARENONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 19:27:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 19:27:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: CO Q10 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:29:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:29:13
Data point term sent to Coder	System	12 Aug 2020 20:28:29
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:27:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: CO Q10 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:06:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:06:12
Data point term sent to Coder	System	11 Aug 2020 15:15:46

FDA-CBER-2022-1614-6156157

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 11:11:02
Name of Medication

Audit	User	Time (GMT)
User entered 'co-q10'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

FDA-CBER-2022-1614-6156158

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 11:11:02
Prophylaxis

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

FDA-CBER-2022-1614-6156159

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 11:11:02
Indication

Audit	User	Time (GMT)
User entered 'supplement' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:27:51
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

FDA-CBER-2022-1614-6156160

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 11:11:02
Dose per administration

Audit	User	Time (GMT)
User entered '100'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

FDA-CBER-2022-1614-6156161

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 11:11:02
Dose unit

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

FDA-CBER-2022-1614-6156162

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 11:11:02
If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

FDA-CBER-2022-1614-6156163

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 11:11:02
Frequency

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

FDA-CBER-2022-1614-6156164

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 11:11:02
If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

FDA-CBER-2022-1614-6156165

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 11:11:02
Route of administration

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

FDA-CBER-2022-1614-6156166

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 11:11:02
If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

FDA-CBER-2022-1614-6156167

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 11:11:02
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:40:55
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 15:15:39
User entered 'un UNK 2018'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

FDA-CBER-2022-1614-6156168

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

FDA-CBER-2022-1614-6156169

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 11:11:02
Ongoing?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

FDA-CBER-2022-1614-6156170

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 11:11:02
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

FDA-CBER-2022-1614-6156171

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 11:11:02
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

FDA-CBER-2022-1614-6156172

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 11:11:02
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:15:39

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:15:39

FDA-CBER-2022-1614-6156174

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:15:39

FDA-CBER-2022-1614-6156175

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 11:11:02
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:29:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:29:13
Data point term sent to Coder	System	12 Aug 2020 20:28:29
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:27:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:17:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:17:11
Data point term sent to Coder	System	11 Aug 2020 15:16:47
User entered 'vitamin d3'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

FDA-CBER-2022-1614-6156176

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 11:11:02
Prophylaxis

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

FDA-CBER-2022-1614-6156177

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 11:11:02
Indication

Audit	User	Time (GMT)
User entered 'supplement' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:27:59
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

FDA-CBER-2022-1614-6156178

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 11:11:02
Dose per administration

Audit	User	Time (GMT)
User entered '1000'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

FDA-CBER-2022-1614-6156179

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 11:11:02
Dose unit

Audit	User	Time (GMT)
User entered 'IU (IU)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

FDA-CBER-2022-1614-6156180

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 11:11:02
If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

FDA-CBER-2022-1614-6156181

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 11:11:02
Frequency

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

FDA-CBER-2022-1614-6156182

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 11:11:02
If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

FDA-CBER-2022-1614-6156183

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 11:11:02
Route of administration

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

FDA-CBER-2022-1614-6156184

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 11:11:02
If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

FDA-CBER-2022-1614-6156185

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 11:11:02
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:40:59
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 15:16:21
User entered 'un UNK 2014'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

FDA-CBER-2022-1614-6156186

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 11:11:02
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

FDA-CBER-2022-1614-6156187

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 11:11:02
Ongoing?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

FDA-CBER-2022-1614-6156188

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 11:11:02
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

FDA-CBER-2022-1614-6156189

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 11:11:02
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

FDA-CBER-2022-1614-6156190

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 11:11:02
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:16:21

FDA-CBER-2022-1614-6156191

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:16:21

FDA-CBER-2022-1614-6156192

US3722066
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 26 Nov 2020 11:11:02
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:16:21

FDA-CBER-2022-1614-6156193

US3722066
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 26 Nov 2020 11:11:02
Were any concomitant procedures performed?

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	24 Sep 2020 21:02:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Aug 2020 13:18:12
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:00:05

FDA-CBER-2022-1614-6156194

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'USA-US083-2020-MRNA-1273-P301000007'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156195

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156196

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156197

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156198

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156199

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156200

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156201

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156202

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Luis'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156203

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'De La Cruz'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156204

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '2 Roper Corners Cir'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156205

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Greenville'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156206

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'SC'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156207

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '29615'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156208

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'US'	System	18 Nov 2020 18:09:42

FDA-CBER-2022-1614-6156209

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '2'	System	20 Nov 2020 16:06:01
User entered '1'	System	18 Nov 2020 18:09:42

FDA-CBER-2022-1614-6156210

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'USA-US083-2020-MRNA-1273-P301000007'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156211

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156212

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156213

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156214

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156215

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156216

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156217

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156218

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Luis'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156219

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'De La Cruz'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156220

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '2 Roper Corners Cir'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156221

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Greenville'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156222

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'SC'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156223

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '29615'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156224

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'US'	System	18 Nov 2020 18:09:42

FDA-CBER-2022-1614-6156225

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '2'	System	20 Nov 2020 16:06:01
User entered '1'	System	18 Nov 2020 18:09:42

FDA-CBER-2022-1614-6156226

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form (1)
Generated On: 26 Nov 2020 11:11:02
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
User entered '18/Nov/2020 18:09'	System	18 Nov 2020 18:09:42

FDA-CBER-2022-1614-6156227

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form (1)
Generated On: 26 Nov 2020 11:11:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 18:09:42

FDA-CBER-2022-1614-6156228

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'USA-US083-2020-MRNA-1273-P301000007'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156229

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156230

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156231

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156232

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156233

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156234

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156235

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156236

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Luis'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156237

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'De La Cruz'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156238

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '2 Roper Corners Cir'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156239

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Greenville'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156240

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'SC'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156241

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '29615'	System	18 Nov 2020 18:08:44

FDA-CBER-2022-1614-6156242

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'US'	System	18 Nov 2020 18:09:42

FDA-CBER-2022-1614-6156243

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 26 Nov 2020 11:11:02
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '2'	System	20 Nov 2020 16:06:01
User entered '1'	System	18 Nov 2020 18:09:42

FDA-CBER-2022-1614-6156244

US3722066
Folder: SAE USA-US083-2020-MRNA-1273-P301000007
Form: Safety Report Form (2)
Generated On: 26 Nov 2020 11:11:02
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
User entered '20/Nov/2020 16:05'	System	20 Nov 2020 16:06:01

FDA-CBER-2022-1614-6156245

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:11:02

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
User entered '1'	(b) (4), (b) (6)	20 Nov 2020 16:06:01