US3752366 (Prod: Baptist Health Center for Clinical Research)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:13:54

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US3752366
Form: Participant Creation
Generated On: 26 Nov 2020 11:13:54

Participant ID	US3752366

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-6191291

US3752366
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-6191292

US3752366
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:13:54

Date of Birth (MMM yyyy)	(b) (6) 1970
Age	49
Age Units	YEARS
Age (Derived)	49
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-2022-1614-6191293

US3752366
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:13:54

Date of Informed Consent *(dd MMM yyyy)*	02 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐ Amendment 2 ☐ Amendment 3 ■ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ■ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ■
If Yes, previous participant number	
Enrollment Trigger	1

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

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Were any significant conditions reported?	Yes ■ No ☐

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US3752366
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:13:54

Condition	ALLERGIC CONJUNCTIVITIS
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	True
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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US3752366
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:13:54

Condition	ALLERGIC RHINITIS
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-2022-1614-6191298

US3752366
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:13:54

Condition	DECOMPRESSION LEFT SUBACROMIAL ARTHROSCOPY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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US3752366
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:13:54

Condition	LASIK EYE SURGERY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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US3752366
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:13:54

Condition	GRADE I CARDIAC MURMUR
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-6191301

US3752366
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	02 SEP 2020
Time of assessment *(00:00-23:59)*	13:28 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 13:28
Height *(xxx.x)*	71 in
Weight *(xxx.x)*	251 lb
BMI *(xxx.x)*	35.08059 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-2022-1614-6191302

US3752366
Folder: Screening
Form: Physical Examination
Generated On: 26 Nov 2020 11:13:54

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	02 SEP 2020

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

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

Location and Living Circumstances Risk (check all that apply)	
No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
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-2022-1614-6191305

US3752366
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-6191306

US3752366
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 11:13:54

What was the date of randomization? *(dd MMM yyyy)*	02 SEP 2020
What was the participant's randomization number?	111046
In what Cohort was the participant enrolled?	>=18 and <65 years and not at risk ● >=18 and <65 years and at risk ○ >=65 years ○

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

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

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Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-6191308

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54

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)*	02 SEP 2020
Time of assessment *(00:00-23:59)*	13:28 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 13:28
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	71 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-6191309

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54

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)*	02 SEP 2020
Time of assessment *(00:00-23:59)*	14:55 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 14:55
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	70 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

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US3752366
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 26 Nov 2020 11:13:54

Was the physical examination performed? Yes ☐ No ■

Date of examination *(dd MMM yyyy)* _____

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

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US3752366
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:13:54

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)*	02 SEP 2020
What was the treatment time? *(00:00-23:59)*	14:18 (24 HR)
Treatment Date and Time (derived)	02 SEP 2020 14:18
Which arm was used to give treatment?	Left Arm ☐ Right Arm ■
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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US3752366
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:13:54

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	02 SEP 2020
Collection time *(00:00-23:59)*	13:40 (24 HR)
Collection date and time (derived)	02 SEP 2020 13:40

FDA-CBER-2022-1614-6191313

Collection date *(dd MMM yyyy)*			02 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:38	02 SEP 2020 13:38
Nasopharyngeal Swab 2	No		

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

FDA-CBER-2022-1614-6191315

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:13:54

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	02 SEP 2020 14:45
PC Open Date & Time	02 SEP 2020 14:38
PC Close Date & Time	02 SEP 2020 17:08

FDA-CBER-2022-1614-6191316

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:13:54

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.9 °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	02 SEP 2020 21:40
PC Open Date & Time	02 SEP 2020 18:03
PC Close Date & Time	03 SEP 2020 11:59

FDA-CBER-2022-1614-6191317

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:13:54

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**	97.5 °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 20:59
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-6191318

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:13:54

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**	98.3 °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	04 SEP 2020 20:36
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

FDA-CBER-2022-1614-6191319

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:13:54

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**	99.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	05 SEP 2020 12:02
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

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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**	101.6 °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	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	06 SEP 2020 19:44
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

FDA-CBER-2022-1614-6191321

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:13:54

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	07 SEP 2020 22:15
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-6191322

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:13:54

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**	98.6 °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	08 SEP 2020 20:57
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-6191323

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:13:54

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	02 SEP 2020 14:46
PC Open Date & Time	02 SEP 2020 14:38
PC Close Date & Time	02 SEP 2020 17:08

FDA-CBER-2022-1614-6191324

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:13:54

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	02 SEP 2020 21:40
PC Open Date & Time	02 SEP 2020 18:03
PC Close Date & Time	03 SEP 2020 11:59

FDA-CBER-2022-1614-6191325

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:13:54

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	03 SEP 2020 20:59
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-6191326

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:13:54

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	04 SEP 2020 20:37
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

FDA-CBER-2022-1614-6191327

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:13:54

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	05 SEP 2020 12:02
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-6191328

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:13:54

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	06 SEP 2020 19:45
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

FDA-CBER-2022-1614-6191329

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:13:54

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	07 SEP 2020 22:15
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-6191330

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:13:54

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	08 SEP 2020 20:57
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-6191331

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-2022-1614-6191332

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:13:54

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	02 SEP 2020 14:46
PC Open Date & Time	02 SEP 2020 14:38
PC Close Date & Time	02 SEP 2020 17:08

FDA-CBER-2022-1614-6191333

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-2022-1614-6191334

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:13:54

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	02 SEP 2020 21:41
PC Open Date & Time	02 SEP 2020 18:03
PC Close Date & Time	03 SEP 2020 11:59

FDA-CBER-2022-1614-6191335

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:13:54

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-2022-1614-6191336

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:13:54

	Yes ☐
PC Time stamp	03 SEP 2020 21:00
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-6191337

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:13:54

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-2022-1614-6191338

	Yes ☐
PC Time stamp	04 SEP 2020 20:37
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

FDA-CBER-2022-1614-6191339

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:13:54

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-2022-1614-6191340

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191341

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:13:54

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-2022-1614-6191342

	Yes ☐
PC Time stamp	06 SEP 2020 19:46
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

FDA-CBER-2022-1614-6191343

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-2022-1614-6191344

	Yes ☐
PC Time stamp	07 SEP 2020 22:16
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:13:54

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-2022-1614-6191346

	Yes ☐
PC Time stamp	08 SEP 2020 20:58
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-6191347

US3752366
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 26 Nov 2020 11:13:54

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **HEADACHE**	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interfererence with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	09 SEP 2020 16:37
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

FDA-CBER-2022-1614-6191348

US3752366
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 26 Nov 2020 11:13:54

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	09 SEP 2020 16:37
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

FDA-CBER-2022-1614-6191349

US3752366
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	9 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-2022-1614-6191350

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

FDA-CBER-2022-1614-6191351

US3752366
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	16 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-2022-1614-6191352

US3752366
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191353

US3752366
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	23 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-6191354

US3752366
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191355

US3752366
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	07 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-6191356

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	07 OCT 2020
Time of assessment *(00:00-23:59)*	13:20 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 13:20
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	76 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-6191357

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54

Timepoint	Pre-Dose ☐ Post-Dose ■
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	

FDA-CBER-2022-1614-6191358

US3752366
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:13:54

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	07 OCT 2020

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

FDA-CBER-2022-1614-6191359

US3752366
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:13:54

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?	
What was the treatment date? *(dd MMM yyyy)*	
What was the treatment time? *(00:00-23:59)*	
Treatment Date and Time (derived)	
Which arm was used to give treatment?	Left Arm ☐ Right Arm ☐
What was the frequency of the study treatment dosing?	
What was the route of administration for the study treatment?	

FDA-CBER-2022-1614-6191360

US3752366
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:13:54

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	07 OCT 2020
Collection time *(00:00-23:59)*	13:47 (24 HR)
Collection date and time (derived)	07 OCT 2020 13:47

FDA-CBER-2022-1614-6191361

Collection date *(dd MMM yyyy)*			07 OCT 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:52	07 OCT 2020 13:52
Nasopharyngeal Swab 2	No		

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

FDA-CBER-2022-1614-6191363

US3752366
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	14 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-6191364

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

FDA-CBER-2022-1614-6191365

US3752366
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54

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-2022-1614-6191366

US3752366
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191367

US3752366
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54

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-2022-1614-6191368

US3752366
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191369

US3752366
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	04 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-6191370

US3752366
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	04 NOV 2020
Time of assessment *(00:00-23:59)*	12:40 (24 HR)
Vital Signs Date and Time (derived)	04 NOV 2020 12:40
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-6191371

US3752366
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:13:54

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	04 NOV 2020

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

FDA-CBER-2022-1614-6191372

US3752366
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:13:54

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	04 NOV 2020
Collection time *(00:00-23:59)*	12:52 (24 HR)
Collection date and time (derived)	04 NOV 2020 12:52

FDA-CBER-2022-1614-6191373

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

FDA-CBER-2022-1614-6191374

US3752366
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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	06 NOV 2020 00:13:25
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

FDA-CBER-2022-1614-6191375

US3752366
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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	11 NOV 2020 06:43:30
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

FDA-CBER-2022-1614-6191376

US3752366
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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	19 NOV 2020 07:50:46
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

FDA-CBER-2022-1614-6191377

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 ☐

FDA-CBER-2022-1614-6191378

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191379

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 ☐

FDA-CBER-2022-1614-6191380

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	06 NOV 2020 00:01
Patient Cloud Close Date & Time	10 NOV 2020 23:59

FDA-CBER-2022-1614-6191381

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-2022-1614-6191382

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2020 00:01
Patient Cloud Close Date & Time	17 NOV 2020 23:59

FDA-CBER-2022-1614-6191383

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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 ☐

FDA-CBER-2022-1614-6191384

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

FDA-CBER-2022-1614-6191385

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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 ☐

FDA-CBER-2022-1614-6191386

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

FDA-CBER-2022-1614-6191387

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 ☐

FDA-CBER-2022-1614-6191388

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191389

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-2022-1614-6191390

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191391

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-6191392

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

FDA-CBER-2022-1614-6191393

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

FDA-CBER-2022-1614-6191394

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191395

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 ☐

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

FDA-CBER-2022-1614-6191397

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 ☐

FDA-CBER-2022-1614-6191398

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191399

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-2022-1614-6191400

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

FDA-CBER-2022-1614-6191401

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 ☐

FDA-CBER-2022-1614-6191402

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191403

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-6191404

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191405

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-6191406

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191407

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 ☐

FDA-CBER-2022-1614-6191408

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

FDA-CBER-2022-1614-6191409

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-2022-1614-6191410

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191411

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

FDA-CBER-2022-1614-6191413

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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-2022-1614-6191414

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191415

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-6191416

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191417

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 ☐

FDA-CBER-2022-1614-6191418

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191419

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191421

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 ☐

FDA-CBER-2022-1614-6191422

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191423

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191425

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 ☐

FDA-CBER-2022-1614-6191426

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191427

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191429

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-2022-1614-6191430

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

FDA-CBER-2022-1614-6191431

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 ☐

FDA-CBER-2022-1614-6191432

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191433

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191435

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 ☐

FDA-CBER-2022-1614-6191436

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

FDA-CBER-2022-1614-6191437

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 ☐

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

FDA-CBER-2022-1614-6191439

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-2022-1614-6191440

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

FDA-CBER-2022-1614-6191441

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-2022-1614-6191442

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

FDA-CBER-2022-1614-6191443

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-2022-1614-6191444

US3752366
Folder: New Safety Follow Up Diary (1)
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2021 00:01
Patient Cloud Close Date & Time	22 JUN 2021 23:59

FDA-CBER-2022-1614-6191445

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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-2022-1614-6191446

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

FDA-CBER-2022-1614-6191447

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-2022-1614-6191448

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191449

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	09 JUL 2021 00:01
Patient Cloud Close Date & Time	13 JUL 2021 23:59

FDA-CBER-2022-1614-6191451

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 ☐

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

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-2022-1614-6191454

US3752366
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Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191455

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191457

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-2022-1614-6191458

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

FDA-CBER-2022-1614-6191459

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-2022-1614-6191460

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

FDA-CBER-2022-1614-6191461

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 ☐

FDA-CBER-2022-1614-6191462

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2021 00:01
Patient Cloud Close Date & Time	24 AUG 2021 23:59

FDA-CBER-2022-1614-6191463

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

FDA-CBER-2022-1614-6191464

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191465

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 ☐

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

FDA-CBER-2022-1614-6191467

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-2022-1614-6191468

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2021 00:01
Patient Cloud Close Date & Time	14 SEP 2021 23:59

FDA-CBER-2022-1614-6191469

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 ☐

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

FDA-CBER-2022-1614-6191471

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 ☐

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

FDA-CBER-2022-1614-6191473

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

FDA-CBER-2022-1614-6191475

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-2022-1614-6191476

US3752366
Folder: New Safety Follow Up Diary (1)
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2021 00:01
Patient Cloud Close Date & Time	12 OCT 2021 23:59

FDA-CBER-2022-1614-6191477

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-2022-1614-6191478

US3752366
Folder: New Safety Follow Up Diary (1)
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

FDA-CBER-2022-1614-6191479

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-2022-1614-6191480

US3752366
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

FDA-CBER-2022-1614-6191481

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-2022-1614-6191482

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

FDA-CBER-2022-1614-6191483

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 ☐

FDA-CBER-2022-1614-6191484

US3752366
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Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191485

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-2022-1614-6191486

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191487

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-2022-1614-6191488

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191489

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191491

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 ☐

FDA-CBER-2022-1614-6191492

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191493

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191495

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-2022-1614-6191496

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191497

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191499

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191501

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191503

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191505

TIMEPOINT	DAY 509
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-6191506

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191507

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191509

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191511

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-2022-1614-6191512

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191513

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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-2022-1614-6191514

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

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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 ☐

FDA-CBER-2022-1614-6191516

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191517

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-2022-1614-6191518

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191519

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-2022-1614-6191520

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

FDA-CBER-2022-1614-6191521

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191523

TIMEPOINT	DAY 572
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-6191524

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191525

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191527

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-2022-1614-6191528

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191529

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191531

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 ☐

FDA-CBER-2022-1614-6191532

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

FDA-CBER-2022-1614-6191533

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-2022-1614-6191534

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191535

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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-2022-1614-6191536

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

FDA-CBER-2022-1614-6191537

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 ☐

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

FDA-CBER-2022-1614-6191539

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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-2022-1614-6191540

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

FDA-CBER-2022-1614-6191541

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191543

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191544

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191545

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191547

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-2022-1614-6191548

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191549

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191551

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-2022-1614-6191552

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191553

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-2022-1614-6191554

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191555

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191557

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-2022-1614-6191558

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191559

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-2022-1614-6191560

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191561

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191563

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-2022-1614-6191564

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191565

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-6191566

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191567

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191569

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

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

FDA-CBER-2022-1614-6191571

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 ☐

FDA-CBER-2022-1614-6191572

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191573

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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-2022-1614-6191574

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191575

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-6191576

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191577

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 ☐

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191579

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-2022-1614-6191580

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

FDA-CBER-2022-1614-6191581

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-2022-1614-6191582

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

FDA-CBER-2022-1614-6191583

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-2022-1614-6191584

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191585

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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-2022-1614-6191586

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191587

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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-2022-1614-6191588

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54

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

FDA-CBER-2022-1614-6191589

US3752366
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54

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-2022-1614-6191590

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

FDA-CBER-2022-1614-6191591

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: COVID-19 Contact
Generated On: 26 Nov 2020 11:13:54

Date of Contact	6 SEP 2020
Time of Contact	17:45
Date and Time of Contact (derived)	6 SEP 2020 17:45
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-2022-1614-6191592

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

FDA-CBER-2022-1614-6191593

	Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	4 SEP 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	99.6 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 ■

	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 ☐

FDA-CBER-2022-1614-6191595

	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-2022-1614-6191596

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 ☐

FDA-CBER-2022-1614-6191597

	Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	5 SEP 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	101.6 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 ■

	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-2022-1614-6191600

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 ☐

FDA-CBER-2022-1614-6191601

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54

	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	6 SEP 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
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-2022-1614-6191602

	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-2022-1614-6191604

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

FDA-CBER-2022-1614-6191605

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54

	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	7 SEP 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
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-2022-1614-6191606

	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-2022-1614-6191608

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

FDA-CBER-2022-1614-6191609

	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	8 SEP 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	98.2 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 ☐

	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 ☐

FDA-CBER-2022-1614-6191611

	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-2022-1614-6191612

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

FDA-CBER-2022-1614-6191613

	Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	9 SEP 2020
Assessment Not Done	False
O2 Saturation	100 %
O2 Saturation Units	%
Temperature	98.1 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 ■

	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 ☐

FDA-CBER-2022-1614-6191615

	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-2022-1614-6191616

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

FDA-CBER-2022-1614-6191617

	Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	10 SEP 2020
Assessment Not Done	False
O2 Saturation	100 %
O2 Saturation Units	%
Temperature	99.0 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 ■

	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 ☐

FDA-CBER-2022-1614-6191619

	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-2022-1614-6191620

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

FDA-CBER-2022-1614-6191621

	Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	11 SEP 2020
Assessment Not Done	False
O2 Saturation	100 %
O2 Saturation Units	%
Temperature	98.2 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 ■

	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 ☐

FDA-CBER-2022-1614-6191623

	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-2022-1614-6191624

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

FDA-CBER-2022-1614-6191625

	Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	12 SEP 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.2 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 ■

	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 ■

FDA-CBER-2022-1614-6191627

	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-2022-1614-6191628

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

FDA-CBER-2022-1614-6191629

	Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	13 SEP 2020
Assessment Not Done	False
O2 Saturation	100 %
O2 Saturation Units	%
Temperature	99.7 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 ■

	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 ☐

FDA-CBER-2022-1614-6191631

	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-2022-1614-6191632

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 ☐

FDA-CBER-2022-1614-6191633

	Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	14 SEP 2020
Assessment Not Done	False
O2 Saturation	100 %
O2 Saturation Units	%
Temperature	98.3 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 ■

	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 ☐

FDA-CBER-2022-1614-6191635

	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-2022-1614-6191636

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

FDA-CBER-2022-1614-6191637

	Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	15 SEP 2020
Assessment Not Done	False
O2 Saturation	100 %
O2 Saturation Units	%
Temperature	98.4 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 ■

	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 ☐

FDA-CBER-2022-1614-6191639

	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-2022-1614-6191640

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 ☐

FDA-CBER-2022-1614-6191641

	Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	16 SEP 2020
Assessment Not Done	False
O2 Saturation	100 %
O2 Saturation Units	%
Temperature	98.1 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 ■

	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 ☐

FDA-CBER-2022-1614-6191643

	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-2022-1614-6191644

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 ☐

FDA-CBER-2022-1614-6191645

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54

	Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	17 SEP 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	97.2 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-2022-1614-6191646

	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 ☐

FDA-CBER-2022-1614-6191647

	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-2022-1614-6191648

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

FDA-CBER-2022-1614-6191649

	Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	18 SEP 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.9 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 ■

	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 ☐

FDA-CBER-2022-1614-6191651

	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-2022-1614-6191652

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

FDA-CBER-2022-1614-6191653

	Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	19 SEP 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	97.0 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 ■

	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 ☐

FDA-CBER-2022-1614-6191655

	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-2022-1614-6191656

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

FDA-CBER-2022-1614-6191657

	Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	20 SEP 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.2 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-2022-1614-6191658

	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 ☐

FDA-CBER-2022-1614-6191659

	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-2022-1614-6191660

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 ☐

FDA-CBER-2022-1614-6191661

	Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	21 SEP 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	97.2 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 ■

	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 ☐

FDA-CBER-2022-1614-6191663

	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-2022-1614-6191664

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:13:54

Date of Visit	8 SEP 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	8 SEP 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-2022-1614-6191665

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	
End Date	
Oxygen Saturation	
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-2022-1614-6191666

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-2022-1614-6191667

Neurologic Dysfunction?	Yes ☐ No ■
Start Date	
Evidence of Pneumonia:	
Clinical Evidence	Yes ☐ No ■
Date of Assessment	
Radiographical Evidence	Yes ☐ No ☐
Date of Assessment	
Admission to an intensive care unit due to SARS-CoV-2	Yes ☐ No ■
Start Date	
End Date	

FDA-CBER-2022-1614-6191668

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Generate Next COVID-19 Assessment
Generated On: 26 Nov 2020 11:13:54

Generate Next COVID-19 Assessment	Yes ☐ No ■

FDA-CBER-2022-1614-6191669

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection
Generated On: 26 Nov 2020 11:13:54

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	10 SEP 2020
Day 5	Yes	12 SEP 2020
Day 7	Yes	14 SEP 2020
Day 9	Yes	16 SEP 2020
Day 14	Yes	21 SEP 2020
Day 21	Yes	28 SEP 2020
Day 28	Yes	7 OCT 2020

FDA-CBER-2022-1614-6191670

US3752366
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SICKD1

FDA-CBER-2022-1614-6191671

US3752366
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	8 SEP 2020
Time of assessment *(00:00-23:59)*	10:20 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 10:20
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	84 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	100 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-6191672

US3752366
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:13:54

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	8 SEP 2020

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

FDA-CBER-2022-1614-6191673

US3752366
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 26 Nov 2020 11:13:54

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ■ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	8 SEP 2020

FDA-CBER-2022-1614-6191674

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	07 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SICKD28

FDA-CBER-2022-1614-6191675

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	07 OCT 2020
Time of assessment *(00:00-23:59)*	13:20 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 13:20
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	76 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-6191676

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:13:54

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	07 OCT 2020

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

FDA-CBER-2022-1614-6191677

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 26 Nov 2020 11:13:54

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ■ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	07 OCT 2020

FDA-CBER-2022-1614-6191678

US3752366
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 26 Nov 2020 11:13:54

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

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-6191679

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54

AEID	USA-US113-2020-MRNA-1273-P30 1000001
Adverse event	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)*	4 SEP 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	16 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ■ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

FDA-CBER-2022-1614-6191680

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

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 26 Nov 2020 11:13:54

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

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

FDA-CBER-2022-1614-6191682

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:13:54

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ■ No ☐
Indication	SUPPLEMENT
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ■ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ■
If frequency is Other, specify	2 TO 3 TIMES PER WEEK
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)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

FDA-CBER-2022-1614-6191684

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ■
Indication	SYMPTOMATIC COVID-19
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-2022-1614-6191685

	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)*	6 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	6 SEP 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

FDA-CBER-2022-1614-6191686

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

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	Intraocular ☐
	Intramuscular ■
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	05 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	05 OCT 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

FDA-CBER-2022-1614-6191688

US3752366
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 26 Nov 2020 11:13:54

Were any concomitant procedures performed?	Yes ☐
	No ☐

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-6191689

US3752366
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 26 Nov 2020 11:13:54

Date of dosing discontinuation (dd MMM yyyy)	8 SEP 2020
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-2022-1614-6191690

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-2022-1614-6191691

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54

SAEID	USA-US113-2020-MRNA-1273-P301000001
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

FDA-CBER-2022-1614-6191692

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form (1)
Generated On: 26 Nov 2020 11:13:54

SAEID	USA-US113-2020-MRNA-1273-P301000001
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/SEP/2020 12:16
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-2022-1614-6191693

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form (2)
Generated On: 26 Nov 2020 11:13:54

SAEID	USA-US113-2020-MRNA-1273-P301000001
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/SEP/2020 09:57
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-2022-1614-6191694

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form (3)
Generated On: 26 Nov 2020 11:13:54

SAEID	USA-US113-2020-MRNA-1273-P301000001
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/SEP/2020 11:12
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-2022-1614-6191695

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form (4)
Generated On: 26 Nov 2020 11:13:54

SAEID	USA-US113-2020-MRNA-1273-P301000001
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	30/SEP/2020 17:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-6191696

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form (5)
Generated On: 26 Nov 2020 11:13:54

SAEID	USA-US113-2020-MRNA-1273-P301000001
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	08/OCT/2020 13:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-6191697

Audit

US3752366 (Prod: Baptist Health Center for Clinical Research)

US3752366
Form: Participant Creation
Generated On: 26 Nov 2020 11:13:54
Participant ID

Audit	User	Time (GMT)
User entered 'US3752366'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:14:51

FDA-CBER-2022-1614-6191699

US3752366
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Was this visit performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 21:00:23

FDA-CBER-2022-1614-6191700

US3752366
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:14:52

FDA-CBER-2022-1614-6191701

US3752366
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	03 Sep 2020 21:00:23

FDA-CBER-2022-1614-6191702

US3752366
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Folder OID

Audit	User	Time (GMT)
User entered 'SCRN'	System	03 Sep 2020 21:00:23

FDA-CBER-2022-1614-6191703

US3752366
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:13:54
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1970'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:14:54

FDA-CBER-2022-1614-6191704

US3752366
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:13:54
Age

Audit	User	Time (GMT)
User entered '49'	(b) (4), (b) (6)	03 Sep 2020 21:00:41

FDA-CBER-2022-1614-6191705

US3752366
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:13:54
Age Units

Audit	User	Time (GMT)
User entered 'YEARS'	System	03 Sep 2020 21:00:41

FDA-CBER-2022-1614-6191706

US3752366
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:13:54
Age (Derived)

Audit	User	Time (GMT)
User entered '49'	System	02 Sep 2020 19:30:17

FDA-CBER-2022-1614-6191707

US3752366
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:13:54
Sex

Audit	User	Time (GMT)
User entered 'Male (M)'	(b) (4), (b) (6)	03 Sep 2020 21:00:41

FDA-CBER-2022-1614-6191708

US3752366
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:13:54
Ethnicity

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	03 Sep 2020 21:00:41

FDA-CBER-2022-1614-6191709

US3752366
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:13:54
White

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	03 Sep 2020 21:00:41

FDA-CBER-2022-1614-6191710

US3752366
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:13:54
Black

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 21:00:41

FDA-CBER-2022-1614-6191711

US3752366
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:13:54
Asian

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 21:00:41

FDA-CBER-2022-1614-6191712

US3752366
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:13:54
American Indian or Alaska Native

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 21:00:41

FDA-CBER-2022-1614-6191713

US3752366
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:13:54
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 21:00:41

FDA-CBER-2022-1614-6191714

US3752366
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:13:54
Other

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 21:00:41

FDA-CBER-2022-1614-6191715

US3752366
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:13:54
If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:00:41

FDA-CBER-2022-1614-6191716

US3752366
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:13:54
Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 21:00:41

FDA-CBER-2022-1614-6191717

US3752366
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 11:13:54
Not reported

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 21:00:41

FDA-CBER-2022-1614-6191718

US3752366
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:13:54
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '02 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 19:30:17

FDA-CBER-2022-1614-6191719

US3752366
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:13:54
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	02 Sep 2020 19:30:17

FDA-CBER-2022-1614-6191720

US3752366
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:13:54
Year of Informed Consent (derived)

Audit	User	Time (GMT)
User entered '2020'	System	02 Sep 2020 19:30:17

FDA-CBER-2022-1614-6191721

US3752366
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:13:54
Protocol Version

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	02 Sep 2020 19:30:17

FDA-CBER-2022-1614-6191722

US3752366
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:13:54
Was participant enrolled in the study?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 19:30:17

FDA-CBER-2022-1614-6191723

US3752366
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:13:54
If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 19:30:17

FDA-CBER-2022-1614-6191724

US3752366
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:13:54
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 19:30:17

FDA-CBER-2022-1614-6191725

US3752366
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:13:54
Was this participant screened previously?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 19:30:17

FDA-CBER-2022-1614-6191726

US3752366
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:13:54
If Yes, previous participant number

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:14:52

FDA-CBER-2022-1614-6191727

US3752366
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 11:13:54
Enrollment Trigger

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 19:30:22

FDA-CBER-2022-1614-6191728

US3752366
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 26 Nov 2020 11:13:54
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 19:30:22

FDA-CBER-2022-1614-6191729

US3752366
Folder: Screening
Form: Medical History Summary
Generated On: 26 Nov 2020 11:13:54
Were any significant conditions reported?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 21:00:58

FDA-CBER-2022-1614-6191730

US3752366
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:13:54
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Ocular infections, irritations and inflammations, HLT: Conjunctival infections, irritations and inflammations, PT: Conjunctivitis allergic, LLT: Allergic conjunctivitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 21:03:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 21:03:45
Data point term sent to Coder	System	03 Sep 2020 21:02:15
User entered 'Allergic conjunctivitis'	(b) (4), (b) (6)	03 Sep 2020 21:01:16

FDA-CBER-2022-1614-6191731

US3752366
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:13:54
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un UNK 1990'	(b) (4), (b) (6)	03 Sep 2020 21:01:16

FDA-CBER-2022-1614-6191732

US3752366
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:13:54
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 21:01:16

FDA-CBER-2022-1614-6191733

US3752366
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:13:54
Condition ongoing at study entry

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please review and confirm if it is ongoing upon study entry. If not, add a stop date if appropriate or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 19:29:33
Query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please review and confirm if it is ongoing upon study entry. If not, add a stop date if appropriate or provide explanation for the Med History duration.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 18:43:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 18:42:57
User opened query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please review and confirm if it is ongoing upon study entry. If not, add a stop date if appropriate or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 15:25:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 21:01:16

FDA-CBER-2022-1614-6191734

US3752366
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:13:54
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:01:16

FDA-CBER-2022-1614-6191735

US3752366
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:13:54
Stop date completely unknown

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 18:42:57
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 21:01:16

FDA-CBER-2022-1614-6191736

US3752366
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:13:54
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	03 Sep 2020 21:01:16

FDA-CBER-2022-1614-6191737

US3752366
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:13:54
Start Year (derived)

Audit	User	Time (GMT)
User entered '1990'	System	03 Sep 2020 21:01:16

FDA-CBER-2022-1614-6191738

US3752366
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:13:54
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:01:16

FDA-CBER-2022-1614-6191739

US3752366
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 11:13:54
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:01:16

FDA-CBER-2022-1614-6191740

US3752366
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:13:54
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 21:03:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 21:03:45
Data point term sent to Coder	System	03 Sep 2020 21:02:15
User entered 'Allergic rhinitis'	(b) (4), (b) (6)	03 Sep 2020 21:01:43

US3752366
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:13:54
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un UNK 1990'	(b) (4), (b) (6)	03 Sep 2020 21:01:43

FDA-CBER-2022-1614-6191742

US3752366
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:13:54
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 21:01:43

FDA-CBER-2022-1614-6191743

US3752366
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:13:54
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 21:01:43

FDA-CBER-2022-1614-6191744

US3752366
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:13:54
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:01:43

FDA-CBER-2022-1614-6191745

US3752366
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:13:54
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 21:01:43

FDA-CBER-2022-1614-6191746

US3752366
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:13:54
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	03 Sep 2020 21:01:43

FDA-CBER-2022-1614-6191747

US3752366
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:13:54
Start Year (derived)

Audit	User	Time (GMT)
User entered '1990'	System	03 Sep 2020 21:01:43

FDA-CBER-2022-1614-6191748

US3752366
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:13:54
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:01:43

FDA-CBER-2022-1614-6191749

US3752366
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 11:13:54
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:01:43

FDA-CBER-2022-1614-6191750

US3752366
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:13:54
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Subacromial decompression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 07:02:39
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 07:02:39
Data point term sent to Coder	System	03 Sep 2020 21:03:21
User entered 'Decompression left subacromial arthroscopy'	(b) (4), (b) (6)	03 Sep 2020 21:03:06

US3752366
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:13:54
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:03:06

FDA-CBER-2022-1614-6191752

US3752366
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:13:54
Start date completely unknown

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	03 Sep 2020 21:03:06

FDA-CBER-2022-1614-6191753

US3752366
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:13:54
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:03:06

FDA-CBER-2022-1614-6191754

US3752366
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:13:54
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:03:06

FDA-CBER-2022-1614-6191755

US3752366
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:13:54
Stop date completely unknown

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	03 Sep 2020 21:03:06

FDA-CBER-2022-1614-6191756

US3752366
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:13:54
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:03:06

FDA-CBER-2022-1614-6191757

US3752366
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:13:54
Start Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:03:06

FDA-CBER-2022-1614-6191758

US3752366
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:13:54
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:03:06

FDA-CBER-2022-1614-6191759

US3752366
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 11:13:54
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:03:06

FDA-CBER-2022-1614-6191760

US3752366
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:13:54
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Keratomileusis, LLT: LASIK eye surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 21:05:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 21:05:40
Data point term sent to Coder	System	03 Sep 2020 21:04:24
User entered 'LASIK eye surgery'	(b) (4), (b) (6)	03 Sep 2020 21:03:23

US3752366
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:13:54
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:03:23

FDA-CBER-2022-1614-6191762

US3752366
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:13:54
Start date completely unknown

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	03 Sep 2020 21:03:23

FDA-CBER-2022-1614-6191763

US3752366
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:13:54
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:03:23

FDA-CBER-2022-1614-6191764

US3752366
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:13:54
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:03:23

FDA-CBER-2022-1614-6191765

US3752366
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:13:54
Stop date completely unknown

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	03 Sep 2020 21:03:23

FDA-CBER-2022-1614-6191766

US3752366
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:13:54
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:03:23

FDA-CBER-2022-1614-6191767

US3752366
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:13:54
Start Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:03:23

FDA-CBER-2022-1614-6191768

US3752366
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:13:54
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:03:23

FDA-CBER-2022-1614-6191769

US3752366
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 11:13:54
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:03:23

FDA-CBER-2022-1614-6191770

US3752366
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:13:54
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Cardiac murmur - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:37:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:37:22
Data point term sent to Coder	System	05 Nov 2020 16:36:20
User entered 'Grade I cardiac murmur'	(b) (4), (b) (6)	05 Nov 2020 16:36:04

US3752366
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:13:54
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:36:04

FDA-CBER-2022-1614-6191772

US3752366
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:13:54
Start date completely unknown

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 16:36:04

FDA-CBER-2022-1614-6191773

US3752366
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:13:54
Condition ongoing at study entry

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 16:36:04

FDA-CBER-2022-1614-6191774

US3752366
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:13:54
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:36:04

FDA-CBER-2022-1614-6191775

US3752366
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:13:54
Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 16:36:04

FDA-CBER-2022-1614-6191776

US3752366
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:13:54
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:36:04

FDA-CBER-2022-1614-6191777

US3752366
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:13:54
Start Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:36:04

FDA-CBER-2022-1614-6191778

US3752366
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:13:54
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:36:04

FDA-CBER-2022-1614-6191779

US3752366
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 11:13:54
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:36:04

FDA-CBER-2022-1614-6191780

US3752366
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 21:04:02

FDA-CBER-2022-1614-6191781

US3752366
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '02 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 21:04:02

FDA-CBER-2022-1614-6191782

US3752366
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '13:28'	(b) (4), (b) (6)	03 Sep 2020 21:04:02

FDA-CBER-2022-1614-6191783

US3752366
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '02 Sep 2020 13:28'	System	03 Sep 2020 21:04:02

FDA-CBER-2022-1614-6191784

US3752366
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Height *(xxx.x)*

Audit	User	Time (GMT)
User entered '71' in	(b) (4), (b) (6)	03 Sep 2020 21:04:02
DataPoint set to visible.	System	02 Sep 2020 19:30:22

FDA-CBER-2022-1614-6191785

US3752366
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Weight *(xxx.x)*

Audit	User	Time (GMT)
User entered '251' lb	(b) (4), (b) (6)	03 Sep 2020 21:04:02
DataPoint set to visible.	System	02 Sep 2020 19:30:22

FDA-CBER-2022-1614-6191786

US3752366
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
BMI *(xxx.x)*

Audit	User	Time (GMT)
User entered '35.08059'	System	03 Sep 2020 21:04:02
DataPoint set to visible.	System	02 Sep 2020 19:30:22

FDA-CBER-2022-1614-6191787

US3752366
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
BMI units

Audit	User	Time (GMT)
User entered 'kg/m2'	System	03 Sep 2020 21:04:02
DataPoint set to visible.	System	02 Sep 2020 19:30:22

FDA-CBER-2022-1614-6191788

US3752366
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Sep 2020 21:04:02

FDA-CBER-2022-1614-6191789

US3752366
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Route of measurement

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:04:02

FDA-CBER-2022-1614-6191790

US3752366
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
If Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:04:02

FDA-CBER-2022-1614-6191791

US3752366
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Pulse *(xxx)*

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Sep 2020 21:04:02

FDA-CBER-2022-1614-6191792

US3752366
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Sep 2020 21:04:02

FDA-CBER-2022-1614-6191793

US3752366
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Sep 2020 21:04:02

FDA-CBER-2022-1614-6191794

US3752366
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Sep 2020 21:04:02

FDA-CBER-2022-1614-6191795

US3752366
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Sep 2020 21:04:02

FDA-CBER-2022-1614-6191796

US3752366
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 21:04:02

FDA-CBER-2022-1614-6191797

US3752366
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Sep 2020 21:04:02

FDA-CBER-2022-1614-6191798

US3752366
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 21:04:02

FDA-CBER-2022-1614-6191799

US3752366
Folder: Screening
Form: Physical Examination
Generated On: 26 Nov 2020 11:13:54
Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:10:33
User entered 'No (N)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Sep 2020 18:09:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 16:06:53
User entered 'No (N)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Sep 2020 13:43:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 21:04:12

US3752366
Folder: Screening
Form: Physical Examination
Generated On: 26 Nov 2020 11:13:54
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:10:33
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 18:09:36
User entered empty; reason for change Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Sep 2020 18:09:36
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 16:06:53
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 16:06:53
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 13:43:57
User entered empty; reason for change Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Sep 2020 13:43:57
Comment added 'Physical exam date and screening date are the same. query?'.	(b) (4), (b) (6)	10 Sep 2020 13:38:30
Comment added 'Physical exam date is the same as screening visit date. Query?'.	(b) (4), (b) (6)	09 Sep 2020 20:05:48
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 16:15:28
User entered '02 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 21:04:12

FDA-CBER-2022-1614-6191801

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 21:05:12

FDA-CBER-2022-1614-6191802

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:05:12

FDA-CBER-2022-1614-6191803

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
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)'	(b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:05:12

FDA-CBER-2022-1614-6191805

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:05:12

FDA-CBER-2022-1614-6191806

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:05:12

FDA-CBER-2022-1614-6191807

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
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)'	(b) (4), (b) (6)	03 Sep 2020 21:05:12

FDA-CBER-2022-1614-6191808

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
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)'	(b) (4), (b) (6)	03 Sep 2020 21:05:12

FDA-CBER-2022-1614-6191809

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:05:12

FDA-CBER-2022-1614-6191810

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
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)'	(b) (4), (b) (6)	03 Sep 2020 21:05:12

FDA-CBER-2022-1614-6191811

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
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)'	(b) (4), (b) (6)	03 Sep 2020 21:05:12

FDA-CBER-2022-1614-6191812

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
Other

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:05:12

FDA-CBER-2022-1614-6191813

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
Specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:05:12

FDA-CBER-2022-1614-6191814

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 21:05:12

FDA-CBER-2022-1614-6191815

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 21:05:12

FDA-CBER-2022-1614-6191816

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
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'	(b) (4), (b) (6)	03 Sep 2020 21:05:12

FDA-CBER-2022-1614-6191817

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 21:05:12

FDA-CBER-2022-1614-6191818

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
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'	(b) (4), (b) (6)	03 Sep 2020 21:05:12

FDA-CBER-2022-1614-6191819

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	03 Sep 2020 21:05:12

FDA-CBER-2022-1614-6191820

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
Other

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 21:05:12

FDA-CBER-2022-1614-6191821

US3752366
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 11:13:54
Specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:05:12

FDA-CBER-2022-1614-6191822

US3752366
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Was this visit performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 21:05:27

FDA-CBER-2022-1614-6191823

US3752366
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '02 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 21:05:27

FDA-CBER-2022-1614-6191824

US3752366
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	03 Sep 2020 21:05:27

FDA-CBER-2022-1614-6191825

US3752366
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Folder OID

Audit	User	Time (GMT)
User entered 'VISIT1'	System	03 Sep 2020 21:05:27

FDA-CBER-2022-1614-6191826

US3752366
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 11:13:54
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:04:53

FDA-CBER-2022-1614-6191827

US3752366
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 11:13:54
What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '111046'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:04:53

FDA-CBER-2022-1614-6191828

US3752366
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 11:13:54
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:04:53

FDA-CBER-2022-1614-6191829

US3752366

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:54

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 16:28:52
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'done' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 21:05:44
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:05:39
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 19:21:29

US3752366
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 11:13:54
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:05:39

FDA-CBER-2022-1614-6191831

US3752366
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 11:13:54
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:05:39

FDA-CBER-2022-1614-6191832

US3752366
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 11:13:54
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:05:39

FDA-CBER-2022-1614-6191833

US3752366
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 11:13:54
Liver Disease

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:05:39

FDA-CBER-2022-1614-6191834

US3752366
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 11:13:54
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 03:42:46
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:05:15
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 15:05:07
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:48:53
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 04:57:18
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:57:15

FDA-CBER-2022-1614-6191835

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 11:13:54
Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191836

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 11:13:54
Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191837

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 11:13:54
Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191838

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 11:13:54
Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191839

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191840

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191841

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '02 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191842

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '13:28'	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191843

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '02 Sep 2020 13:28'	System	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191844

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User entered '98.0' F	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191845

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Route of measurement

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:47
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Sep 2020 21:06:47
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:06:47
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191846

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
If Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191847

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Pulse *(xxx)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:47
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Sep 2020 21:06:47
User entered '71' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:06:47
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191848

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Sep 2020 21:06:47
User entered empty.	System	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191849

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:47
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Sep 2020 21:06:47
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:06:47
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191850

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Sep 2020 21:06:47
User entered empty.	System	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191851

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:47
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Sep 2020 21:06:47
User entered '112' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:06:47
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191852

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 21:06:47
User entered empty.	System	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191853

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:47
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Sep 2020 21:06:47
User entered '78' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:06:47
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191854

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 21:06:47
User entered empty.	System	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191855

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 11:13:54
Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191856

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 11:13:54
Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191857

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191858

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191859

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '02 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191860

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:07:36
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Sep 2020 21:07:36
User entered '14:55' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:07:36
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191861

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '02 Sep 2020 14:55'	System	03 Sep 2020 21:07:36
User entered empty.	System	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191862

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:07:36
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Sep 2020 21:07:36
User entered '98.3' F reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:07:36
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191863

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Route of measurement

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:07:36
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191864

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
If Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191865

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Pulse *(xxx)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:07:36
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Sep 2020 21:07:36
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:07:36
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191866

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Sep 2020 21:07:36
User entered empty.	System	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191867

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:07:36
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Sep 2020 21:07:36
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:07:36
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191868

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Sep 2020 21:07:36
User entered empty.	System	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191869

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:07:36
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Sep 2020 21:07:36
User entered '128' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:07:36
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191870

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 21:07:36
User entered empty.	System	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191871

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:07:36
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Sep 2020 21:07:36
User entered '78' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:07:36
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191872

US3752366
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 21:07:36
User entered empty.	System	03 Sep 2020 21:06:22

FDA-CBER-2022-1614-6191873

US3752366
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 26 Nov 2020 11:13:54
Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 14:39:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Sep 2020 18:11:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 16:07:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Sep 2020 13:44:25
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:07:43

US3752366
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 26 Nov 2020 11:13:54
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 14:39:52
User entered '02 Sep 2020' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Sep 2020 18:11:08
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 16:07:24
User entered '02 Sep 2020' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Sep 2020 13:44:25
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:07:43

US3752366
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:13:54
Was study treatment given?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191876

US3752366
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:13:54
If No, reason not given

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191877

US3752366
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:13:54
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191878

US3752366
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:13:54
What was the study treatment?

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191879

US3752366
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:13:54
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '02 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191880

US3752366
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:13:54
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '14:18'	(b) (4), (b) (6)	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191881

US3752366
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:13:54
Treatment Date and Time (derived)

Audit	User	Time (GMT)
User entered '02 Sep 2020 14:18'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191882

US3752366
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:13:54
Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191883

US3752366
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:13:54
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191884

US3752366
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 11:13:54
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191885

US3752366
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:13:54
Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 21:08:07

FDA-CBER-2022-1614-6191886

US3752366
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:13:54
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '02 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 21:08:07

FDA-CBER-2022-1614-6191887

US3752366
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:13:54
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '13:40'	(b) (4), (b) (6)	03 Sep 2020 21:08:07

FDA-CBER-2022-1614-6191888

US3752366
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:13:54
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '02 Sep 2020 13:40'	System	03 Sep 2020 21:08:07

FDA-CBER-2022-1614-6191889

US3752366
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 26 Nov 2020 11:13:54
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '02 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 21:08:23

FDA-CBER-2022-1614-6191890

US3752366
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 11:13:54
Lab Test

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	03 Sep 2020 21:08:23

FDA-CBER-2022-1614-6191891

US3752366
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 11:13:54
Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 21:08:23

FDA-CBER-2022-1614-6191892

US3752366
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 11:13:54
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
User entered '13:38'	(b) (4), (b) (6)	03 Sep 2020 21:08:23

FDA-CBER-2022-1614-6191893

US3752366
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 11:13:54
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '02 Sep 2020 13:38'	System	03 Sep 2020 21:08:23

FDA-CBER-2022-1614-6191894

US3752366
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 11:13:54
Lab Test

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	03 Sep 2020 21:08:23

FDA-CBER-2022-1614-6191895

US3752366
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 11:13:54
Was the sample collected?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:08:23

FDA-CBER-2022-1614-6191896

US3752366
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 11:13:54
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:08:23

FDA-CBER-2022-1614-6191897

US3752366
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 11:13:54
Collection date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:08:23

FDA-CBER-2022-1614-6191898

US3752366
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 26 Nov 2020 11:13:54
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 21:08:28

FDA-CBER-2022-1614-6191899

US3752366
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 26 Nov 2020 11:13:54
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 21:08:28

FDA-CBER-2022-1614-6191900

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191901

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:45:20', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b42d265f-c666-479e-9957-f3c1ba5c207f'	System	02 Sep 2020 19:45:39
User entered 'Yes (Y)'	System	02 Sep 2020 19:45:39

FDA-CBER-2022-1614-6191902

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:45:26', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b42d265f-c666-479e-9957-f3c1ba5c207f'	System	02 Sep 2020 19:45:39
User entered '98.3'	System	02 Sep 2020 19:45:39

FDA-CBER-2022-1614-6191903

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:45:31', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b42d265f-c666-479e-9957-f3c1ba5c207f'	System	02 Sep 2020 19:45:39
User entered 'No (N)'	System	02 Sep 2020 19:45:39

FDA-CBER-2022-1614-6191904

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:45:38', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b42d265f-c666-479e-9957-f3c1ba5c207f'	System	02 Sep 2020 19:45:39
User entered '02 Sep 2020 14:45'	System	02 Sep 2020 19:45:39

FDA-CBER-2022-1614-6191905

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 14:38'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191906

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 17:08'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191907

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191908

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:11', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '9667ddf2-689d-4933-a27c-1b83877a1105'	System	03 Sep 2020 02:40:27
User entered 'Yes (Y)'	System	03 Sep 2020 02:40:27

FDA-CBER-2022-1614-6191909

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:16', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '9667ddf2-689d-4933-a27c-1b83877a1105'	System	03 Sep 2020 02:40:27
User entered '97.9'	System	03 Sep 2020 02:40:27

FDA-CBER-2022-1614-6191910

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:19', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '9667ddf2-689d-4933-a27c-1b83877a1105'	System	03 Sep 2020 02:40:27
User entered 'No (N)'	System	03 Sep 2020 02:40:27

FDA-CBER-2022-1614-6191911

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:22', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '9667ddf2-689d-4933-a27c-1b83877a1105'	System	03 Sep 2020 02:40:27
User entered '02 Sep 2020 21:40'	System	03 Sep 2020 02:40:27

FDA-CBER-2022-1614-6191912

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 18:03'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191913

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191914

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 2'	System	02 Sep 2020 19:31:46

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:13:54
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:13', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '13e7ded5-abcf-4819-9519-2c860531bfbf'	System	04 Sep 2020 01:59:27
User entered 'Yes (Y)'	System	04 Sep 2020 01:59:27

FDA-CBER-2022-1614-6191916

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:13:54
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:17', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '13e7ded5-abcf-4819-9519-2c860531bfbf'	System	04 Sep 2020 01:59:27
User entered '97.5'	System	04 Sep 2020 01:59:27

FDA-CBER-2022-1614-6191917

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:13:54
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:20', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '13e7ded5-abcf-4819-9519-2c860531bfbf'	System	04 Sep 2020 01:59:27
User entered 'No (N)'	System	04 Sep 2020 01:59:27

FDA-CBER-2022-1614-6191918

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:13:54
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:24', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '13e7ded5-abcf-4819-9519-2c860531bfbf'	System	04 Sep 2020 01:59:27
User entered '03 Sep 2020 20:59'	System	04 Sep 2020 01:59:27

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191920

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191921

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 3'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191922

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:13:54
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:36:24', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '120655b4-08e5-4c60-ae31-737c35dc6b4e'	System	05 Sep 2020 01:36:39
User entered 'Yes (Y)'	System	05 Sep 2020 01:36:39

FDA-CBER-2022-1614-6191923

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:13:54
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:36:28', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '120655b4-08e5-4c60-ae31-737c35dc6b4e'	System	05 Sep 2020 01:36:39
User entered '98.3'	System	05 Sep 2020 01:36:39

FDA-CBER-2022-1614-6191924

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:13:54
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:36:32', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '120655b4-08e5-4c60-ae31-737c35dc6b4e'	System	05 Sep 2020 01:36:39
User entered 'No (N)'	System	05 Sep 2020 01:36:39

FDA-CBER-2022-1614-6191925

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:13:54
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:36:36', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '120655b4-08e5-4c60-ae31-737c35dc6b4e'	System	05 Sep 2020 01:36:39
User entered '04 Sep 2020 20:36'	System	05 Sep 2020 01:36:39

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191927

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191928

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 4'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191929

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:13:54
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:02:05', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'db2b169b-456d-4d4e-a25c-225bd90b88ca'	System	05 Sep 2020 17:02:44
User entered 'Yes (Y)'	System	05 Sep 2020 17:02:44

FDA-CBER-2022-1614-6191930

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:13:54
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:02:11', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'db2b169b-456d-4d4e-a25c-225bd90b88ca'	System	05 Sep 2020 17:02:44
User entered '99.6'	System	05 Sep 2020 17:02:44

FDA-CBER-2022-1614-6191931

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:13:54
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:02:15', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'db2b169b-456d-4d4e-a25c-225bd90b88ca'	System	05 Sep 2020 17:02:44
User entered 'No (N)'	System	05 Sep 2020 17:02:44

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:13:54
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:02:35', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'db2b169b-456d-4d4e-a25c-225bd90b88ca'	System	05 Sep 2020 17:02:44
User entered '05 Sep 2020 12:02'	System	05 Sep 2020 17:02:44

FDA-CBER-2022-1614-6191933

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191934

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191935

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 5'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191936

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:13:54
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:44:30', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1b46e0a5-a15a-44cc-8d74-35fe944d5dd2'	System	07 Sep 2020 00:44:56
User entered 'Yes (Y)'	System	07 Sep 2020 00:44:56

FDA-CBER-2022-1614-6191937

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:13:54
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:44:34', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1b46e0a5-a15a-44cc-8d74-35fe944d5dd2'	System	07 Sep 2020 00:44:56
User entered '101.6'	System	07 Sep 2020 00:44:56

FDA-CBER-2022-1614-6191938

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:13:54
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:44:38', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1b46e0a5-a15a-44cc-8d74-35fe944d5dd2'	System	07 Sep 2020 00:44:56
User entered 'Yes (Y)'	System	07 Sep 2020 00:44:56

FDA-CBER-2022-1614-6191939

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:13:54
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 15:04:47
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'TYLENOL ADDED TO CONCOMITANT MEDICATIONS' (Site from System).	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:03:16
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	07 Sep 2020 00:44:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:44:44', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1b46e0a5-a15a-44cc-8d74-35fe944d5dd2'	System	07 Sep 2020 00:44:56
User entered '1'	System	07 Sep 2020 00:44:56

FDA-CBER-2022-1614-6191940

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:13:54
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:44:44', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1b46e0a5-a15a-44cc-8d74-35fe944d5dd2'	System	07 Sep 2020 00:44:56
User entered '0'	System	07 Sep 2020 00:44:56

FDA-CBER-2022-1614-6191941

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:13:54
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:44:52', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1b46e0a5-a15a-44cc-8d74-35fe944d5dd2'	System	07 Sep 2020 00:44:56
User entered '06 Sep 2020 19:44'	System	07 Sep 2020 00:44:56

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191943

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191944

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 6'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191945

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:13:54
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:14:05', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '6348b54b-4fb6-4b17-b9ad-d4470a985b50'	System	08 Sep 2020 03:15:12
User entered 'Yes (Y)'	System	08 Sep 2020 03:15:12

FDA-CBER-2022-1614-6191946

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:13:54
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:15:02', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '6348b54b-4fb6-4b17-b9ad-d4470a985b50'	System	08 Sep 2020 03:15:12
User entered '98.0'	System	08 Sep 2020 03:15:12

FDA-CBER-2022-1614-6191947

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:13:54
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:15:04', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '6348b54b-4fb6-4b17-b9ad-d4470a985b50'	System	08 Sep 2020 03:15:12
User entered 'No (N)'	System	08 Sep 2020 03:15:12

FDA-CBER-2022-1614-6191948

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:13:54
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:15:07', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '6348b54b-4fb6-4b17-b9ad-d4470a985b50'	System	08 Sep 2020 03:15:12
User entered '07 Sep 2020 22:15'	System	08 Sep 2020 03:15:12

FDA-CBER-2022-1614-6191949

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191950

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191951

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 7'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191952

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:13:54
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:56:51', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '40a304f0-cfa4-4638-a20f-117dc2de3ca6'	System	09 Sep 2020 01:57:05
User entered 'Yes (Y)'	System	09 Sep 2020 01:57:05

FDA-CBER-2022-1614-6191953

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:13:54
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:56:56', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '40a304f0-cfa4-4638-a20f-117dc2de3ca6'	System	09 Sep 2020 01:57:05
User entered '98.6'	System	09 Sep 2020 01:57:05

FDA-CBER-2022-1614-6191954

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:13:54
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:56:58', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '40a304f0-cfa4-4638-a20f-117dc2de3ca6'	System	09 Sep 2020 01:57:05
User entered 'No (N)'	System	09 Sep 2020 01:57:05

FDA-CBER-2022-1614-6191955

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:13:54
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:57:01', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '40a304f0-cfa4-4638-a20f-117dc2de3ca6'	System	09 Sep 2020 01:57:05
User entered '08 Sep 2020 20:57'	System	09 Sep 2020 01:57:05

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191957

US3752366
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191958

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191959

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-02T14:45:48', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '335bd944-4179-42f6-b670-6b0824375c48'	System	02 Sep 2020 19:46:08
User entered 'None (1)'	System	02 Sep 2020 19:46:08

FDA-CBER-2022-1614-6191960

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:45:51', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '335bd944-4179-42f6-b670-6b0824375c48'	System	02 Sep 2020 19:46:08
User entered 'No (N)'	System	02 Sep 2020 19:46:08

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:45:54', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '335bd944-4179-42f6-b670-6b0824375c48'	System	02 Sep 2020 19:46:08
User entered 'No (N)'	System	02 Sep 2020 19:46:08

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-02T14:45:59', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '335bd944-4179-42f6-b670-6b0824375c48'	System	02 Sep 2020 19:46:08
User entered 'None (1)'	System	02 Sep 2020 19:46:08

FDA-CBER-2022-1614-6191963

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:46:05', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '335bd944-4179-42f6-b670-6b0824375c48'	System	02 Sep 2020 19:46:08
User entered '02 Sep 2020 14:46'	System	02 Sep 2020 19:46:08

FDA-CBER-2022-1614-6191964

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 14:38'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191965

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 17:08'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191966

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191967

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-02T21:40:29', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'e46f59ff-cff2-494b-90b1-f0b380179cbb'	System	03 Sep 2020 02:40:50
User entered 'None (1)'	System	03 Sep 2020 02:40:50

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:31', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'e46f59ff-cff2-494b-90b1-f0b380179cbb'	System	03 Sep 2020 02:40:50
User entered 'No (N)'	System	03 Sep 2020 02:40:50

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:33', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'e46f59ff-cff2-494b-90b1-f0b380179cbb'	System	03 Sep 2020 02:40:50
User entered 'No (N)'	System	03 Sep 2020 02:40:50

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-02T21:40:35', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'e46f59ff-cff2-494b-90b1-f0b380179cbb'	System	03 Sep 2020 02:40:50
User entered 'None (1)'	System	03 Sep 2020 02:40:50

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:47', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'e46f59ff-cff2-494b-90b1-f0b380179cbb'	System	03 Sep 2020 02:40:50
User entered '02 Sep 2020 21:40'	System	03 Sep 2020 02:40:50

FDA-CBER-2022-1614-6191972

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 18:03'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191973

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191974

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 2'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191975

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-03T20:59:36', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '39a7e73f-3e1e-4a9f-8536-99e66ab1ef4f'	System	04 Sep 2020 01:59:48
User entered 'None (1)'	System	04 Sep 2020 01:59:48

FDA-CBER-2022-1614-6191976

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:13:54
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:38', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '39a7e73f-3e1e-4a9f-8536-99e66ab1ef4f'	System	04 Sep 2020 01:59:48
User entered 'No (N)'	System	04 Sep 2020 01:59:48

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:13:54
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:40', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '39a7e73f-3e1e-4a9f-8536-99e66ab1ef4f'	System	04 Sep 2020 01:59:48
User entered 'No (N)'	System	04 Sep 2020 01:59:48

FDA-CBER-2022-1614-6191978

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-03T20:59:42', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '39a7e73f-3e1e-4a9f-8536-99e66ab1ef4f'	System	04 Sep 2020 01:59:48
User entered 'None (1)'	System	04 Sep 2020 01:59:48

FDA-CBER-2022-1614-6191979

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:13:54
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:44', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '39a7e73f-3e1e-4a9f-8536-99e66ab1ef4f'	System	04 Sep 2020 01:59:48
User entered '03 Sep 2020 20:59'	System	04 Sep 2020 01:59:48

FDA-CBER-2022-1614-6191980

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191981

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191982

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 3'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191983

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-04T20:36:50', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '0a43deb6-1064-4280-8965-c33b22c51499'	System	05 Sep 2020 01:37:03
User entered 'None (1)'	System	05 Sep 2020 01:37:03

FDA-CBER-2022-1614-6191984

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:13:54
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:36:52', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '0a43deb6-1064-4280-8965-c33b22c51499'	System	05 Sep 2020 01:37:03
User entered 'No (N)'	System	05 Sep 2020 01:37:03

FDA-CBER-2022-1614-6191985

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:13:54
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:36:55', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '0a43deb6-1064-4280-8965-c33b22c51499'	System	05 Sep 2020 01:37:03
User entered 'No (N)'	System	05 Sep 2020 01:37:03

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-04T20:36:56', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '0a43deb6-1064-4280-8965-c33b22c51499'	System	05 Sep 2020 01:37:03
User entered 'None (1)'	System	05 Sep 2020 01:37:03

FDA-CBER-2022-1614-6191987

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:13:54
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:37:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '0a43deb6-1064-4280-8965-c33b22c51499'	System	05 Sep 2020 01:37:03
User entered '04 Sep 2020 20:37'	System	05 Sep 2020 01:37:03

FDA-CBER-2022-1614-6191988

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191989

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191990

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 4'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191991

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-05T12:02:39', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'ca65d1b6-cfe7-4b87-b8fa-4c7804b20c19'	System	05 Sep 2020 17:02:54
User entered 'None (1)'	System	05 Sep 2020 17:02:54

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:13:54
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:02:42', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'ca65d1b6-cfe7-4b87-b8fa-4c7804b20c19'	System	05 Sep 2020 17:02:54
User entered 'No (N)'	System	05 Sep 2020 17:02:54

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:13:54
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:02:44', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'ca65d1b6-cfe7-4b87-b8fa-4c7804b20c19'	System	05 Sep 2020 17:02:54
User entered 'No (N)'	System	05 Sep 2020 17:02:54

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-05T12:02:46', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'ca65d1b6-cfe7-4b87-b8fa-4c7804b20c19'	System	05 Sep 2020 17:02:54
User entered 'None (1)'	System	05 Sep 2020 17:02:54

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:13:54
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:02:50', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'ca65d1b6-cfe7-4b87-b8fa-4c7804b20c19'	System	05 Sep 2020 17:02:54
User entered '05 Sep 2020 12:02'	System	05 Sep 2020 17:02:54

FDA-CBER-2022-1614-6191996

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191997

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191998

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 5'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6191999

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-06T19:44:56', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '4acca04a-866c-48a8-ae5b-9c53204145e1'	System	07 Sep 2020 00:45:11
User entered 'None (1)'	System	07 Sep 2020 00:45:11

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:13:54
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:44:58', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '4acca04a-866c-48a8-ae5b-9c53204145e1'	System	07 Sep 2020 00:45:11
User entered 'No (N)'	System	07 Sep 2020 00:45:11

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:13:54
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:45:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '4acca04a-866c-48a8-ae5b-9c53204145e1'	System	07 Sep 2020 00:45:11
User entered 'No (N)'	System	07 Sep 2020 00:45:11

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-06T19:45:02', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '4acca04a-866c-48a8-ae5b-9c53204145e1'	System	07 Sep 2020 00:45:11
User entered 'None (1)'	System	07 Sep 2020 00:45:11

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:13:54
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:45:06', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '4acca04a-866c-48a8-ae5b-9c53204145e1'	System	07 Sep 2020 00:45:11
User entered '06 Sep 2020 19:45'	System	07 Sep 2020 00:45:11

FDA-CBER-2022-1614-6192004

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192005

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192006

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 6'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192007

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-07T22:15:11', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '15598095-1267-4d45-a853-5e7909abd0e2'	System	08 Sep 2020 03:15:40
User entered 'None (1)'	System	08 Sep 2020 03:15:40

FDA-CBER-2022-1614-6192008

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:13:54
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:15:14', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '15598095-1267-4d45-a853-5e7909abd0e2'	System	08 Sep 2020 03:15:40
User entered 'No (N)'	System	08 Sep 2020 03:15:40

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:13:54
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:15:32', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '15598095-1267-4d45-a853-5e7909abd0e2'	System	08 Sep 2020 03:15:40
User entered 'No (N)'	System	08 Sep 2020 03:15:40

FDA-CBER-2022-1614-6192010

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-07T22:15:33', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '15598095-1267-4d45-a853-5e7909abd0e2'	System	08 Sep 2020 03:15:40
User entered 'None (1)'	System	08 Sep 2020 03:15:40

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:13:54
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:15:37', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '15598095-1267-4d45-a853-5e7909abd0e2'	System	08 Sep 2020 03:15:40
User entered '07 Sep 2020 22:15'	System	08 Sep 2020 03:15:40

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192013

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192014

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 7'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192015

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-08T20:57:06', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'a2abdf80-7ef8-4229-ad36-5b11db47396d'	System	09 Sep 2020 01:57:20
User entered 'None (1)'	System	09 Sep 2020 01:57:20

FDA-CBER-2022-1614-6192016

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:13:54
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:57:09', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'a2abdf80-7ef8-4229-ad36-5b11db47396d'	System	09 Sep 2020 01:57:20
User entered 'No (N)'	System	09 Sep 2020 01:57:20

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:13:54
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:57:11', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'a2abdf80-7ef8-4229-ad36-5b11db47396d'	System	09 Sep 2020 01:57:20
User entered 'No (N)'	System	09 Sep 2020 01:57:20

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-08T20:57:12', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'a2abdf80-7ef8-4229-ad36-5b11db47396d'	System	09 Sep 2020 01:57:20
User entered 'None (1)'	System	09 Sep 2020 01:57:20

FDA-CBER-2022-1614-6192019

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:13:54
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:57:16', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'a2abdf80-7ef8-4229-ad36-5b11db47396d'	System	09 Sep 2020 01:57:20
User entered '08 Sep 2020 20:57'	System	09 Sep 2020 01:57:20

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192021

US3752366
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192022

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192023

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:46:13', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '603fd5e9-cff0-41b2-a686-3abdb4e4491c'	System	02 Sep 2020 19:46:42
User entered 'None (0)'	System	02 Sep 2020 19:46:42

FDA-CBER-2022-1614-6192024

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:46:17', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '603fd5e9-cff0-41b2-a686-3abdb4e4491c'	System	02 Sep 2020 19:46:42
User entered 'None (0)'	System	02 Sep 2020 19:46:42

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:46:21', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '603fd5e9-cff0-41b2-a686-3abdb4e4491c'	System	02 Sep 2020 19:46:42
User entered 'None (0)'	System	02 Sep 2020 19:46:42

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:46:24', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '603fd5e9-cff0-41b2-a686-3abdb4e4491c'	System	02 Sep 2020 19:46:42
User entered 'None (0)'	System	02 Sep 2020 19:46:42

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:46:26', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '603fd5e9-cff0-41b2-a686-3abdb4e4491c'	System	02 Sep 2020 19:46:42
User entered 'None (0)'	System	02 Sep 2020 19:46:42

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:46:29', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '603fd5e9-cff0-41b2-a686-3abdb4e4491c'	System	02 Sep 2020 19:46:42
User entered 'None (0)'	System	02 Sep 2020 19:46:42

FDA-CBER-2022-1614-6192029

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-02T14:46:35', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '603fd5e9-cff0-41b2-a686-3abdb4e4491c'	System	02 Sep 2020 19:46:42
User entered 'No (N)'	System	02 Sep 2020 19:46:42

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:46:40', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '603fd5e9-cff0-41b2-a686-3abdb4e4491c'	System	02 Sep 2020 19:46:42
User entered '02 Sep 2020 14:46'	System	02 Sep 2020 19:46:42

FDA-CBER-2022-1614-6192031

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 14:38'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192032

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 17:08'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192033

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192034

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:52', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'fda6cdc9-ae8f-4c3d-a405-378d368af507'	System	03 Sep 2020 02:41:11
User entered 'None (0)'	System	03 Sep 2020 02:41:11

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:55', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'fda6cdc9-ae8f-4c3d-a405-378d368af507'	System	03 Sep 2020 02:41:11
User entered 'None (0)'	System	03 Sep 2020 02:41:11

FDA-CBER-2022-1614-6192036

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:57', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'fda6cdc9-ae8f-4c3d-a405-378d368af507'	System	03 Sep 2020 02:41:11
User entered 'None (0)'	System	03 Sep 2020 02:41:11

FDA-CBER-2022-1614-6192037

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:59', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'fda6cdc9-ae8f-4c3d-a405-378d368af507'	System	03 Sep 2020 02:41:11
User entered 'None (0)'	System	03 Sep 2020 02:41:11

FDA-CBER-2022-1614-6192038

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:41:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'fda6cdc9-ae8f-4c3d-a405-378d368af507'	System	03 Sep 2020 02:41:11
User entered 'None (0)'	System	03 Sep 2020 02:41:11

FDA-CBER-2022-1614-6192039

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:41:02', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'fda6cdc9-ae8f-4c3d-a405-378d368af507'	System	03 Sep 2020 02:41:11
User entered 'None (0)'	System	03 Sep 2020 02:41:11

FDA-CBER-2022-1614-6192040

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-02T21:41:05', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'fda6cdc9-ae8f-4c3d-a405-378d368af507'	System	03 Sep 2020 02:41:11
User entered 'No (N)'	System	03 Sep 2020 02:41:11

FDA-CBER-2022-1614-6192041

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:41:08', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'fda6cdc9-ae8f-4c3d-a405-378d368af507'	System	03 Sep 2020 02:41:11
User entered '02 Sep 2020 21:41'	System	03 Sep 2020 02:41:11

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 18:03'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192043

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192044

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 2'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192045

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:13:54
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:48', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd2fe776f-1835-4b81-a7eb-8fe1327841b2'	System	04 Sep 2020 02:00:20
User entered 'None (0)'	System	04 Sep 2020 02:00:20

FDA-CBER-2022-1614-6192046

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:13:54
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:49', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd2fe776f-1835-4b81-a7eb-8fe1327841b2'	System	04 Sep 2020 02:00:20
User entered 'None (0)'	System	04 Sep 2020 02:00:20

FDA-CBER-2022-1614-6192047

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:13:54
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:51', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd2fe776f-1835-4b81-a7eb-8fe1327841b2'	System	04 Sep 2020 02:00:20
User entered 'None (0)'	System	04 Sep 2020 02:00:20

FDA-CBER-2022-1614-6192048

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:13:54
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:53', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd2fe776f-1835-4b81-a7eb-8fe1327841b2'	System	04 Sep 2020 02:00:20
User entered 'None (0)'	System	04 Sep 2020 02:00:20

FDA-CBER-2022-1614-6192049

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:13:54
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:54', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd2fe776f-1835-4b81-a7eb-8fe1327841b2'	System	04 Sep 2020 02:00:20
User entered 'None (0)'	System	04 Sep 2020 02:00:20

FDA-CBER-2022-1614-6192050

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:13:54
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:56', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd2fe776f-1835-4b81-a7eb-8fe1327841b2'	System	04 Sep 2020 02:00:20
User entered 'None (0)'	System	04 Sep 2020 02:00:20

FDA-CBER-2022-1614-6192051

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-03T20:59:59', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd2fe776f-1835-4b81-a7eb-8fe1327841b2'	System	04 Sep 2020 02:00:20
User entered 'No (N)'	System	04 Sep 2020 02:00:20

FDA-CBER-2022-1614-6192052

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:13:54
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T21:00:03', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd2fe776f-1835-4b81-a7eb-8fe1327841b2'	System	04 Sep 2020 02:00:20
User entered '03 Sep 2020 21:00'	System	04 Sep 2020 02:00:20

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192054

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192055

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 3'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192056

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:13:54
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:37:10', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2969b99b-ec61-4887-9d3d-188e6e642186'	System	05 Sep 2020 01:37:37
User entered 'No interference with activity (1)'	System	05 Sep 2020 01:37:37

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:13:54
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:37:14', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2969b99b-ec61-4887-9d3d-188e6e642186'	System	05 Sep 2020 01:37:37
User entered 'None (0)'	System	05 Sep 2020 01:37:37

FDA-CBER-2022-1614-6192058

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:13:54
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:37:16', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2969b99b-ec61-4887-9d3d-188e6e642186'	System	05 Sep 2020 01:37:37
User entered 'None (0)'	System	05 Sep 2020 01:37:37

FDA-CBER-2022-1614-6192059

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:13:54
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:37:18', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2969b99b-ec61-4887-9d3d-188e6e642186'	System	05 Sep 2020 01:37:37
User entered 'None (0)'	System	05 Sep 2020 01:37:37

FDA-CBER-2022-1614-6192060

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:13:54
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:37:21', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2969b99b-ec61-4887-9d3d-188e6e642186'	System	05 Sep 2020 01:37:37
User entered 'None (0)'	System	05 Sep 2020 01:37:37

FDA-CBER-2022-1614-6192061

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:13:54
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:37:23', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2969b99b-ec61-4887-9d3d-188e6e642186'	System	05 Sep 2020 01:37:37
User entered 'None (0)'	System	05 Sep 2020 01:37:37

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-04T20:37:27', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2969b99b-ec61-4887-9d3d-188e6e642186'	System	05 Sep 2020 01:37:37
User entered 'No (N)'	System	05 Sep 2020 01:37:37

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:13:54
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:37:31', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2969b99b-ec61-4887-9d3d-188e6e642186'	System	05 Sep 2020 01:37:37
User entered '04 Sep 2020 20:37'	System	05 Sep 2020 01:37:37

FDA-CBER-2022-1614-6192064

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192065

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192066

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 4'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192067

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:13:54
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:03:02', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '5bfe111e-7ca3-49bc-ad78-b8fb91c3f6da'	System	05 Sep 2020 17:05:34
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	05 Sep 2020 17:05:34

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:13:54
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:03:27', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '5bfe111e-7ca3-49bc-ad78-b8fb91c3f6da'	System	05 Sep 2020 17:05:34
User entered 'Some interference with activity (2)'	System	05 Sep 2020 17:05:34

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:13:54
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:03:41', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '5bfe111e-7ca3-49bc-ad78-b8fb91c3f6da'	System	05 Sep 2020 17:05:34
User entered 'None (0)'	System	05 Sep 2020 17:05:34

FDA-CBER-2022-1614-6192070

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:13:54
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:03:49', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '5bfe111e-7ca3-49bc-ad78-b8fb91c3f6da'	System	05 Sep 2020 17:05:34
User entered 'No interference with activity (1)'	System	05 Sep 2020 17:05:34

FDA-CBER-2022-1614-6192071

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:13:54
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:03:52', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '5bfe111e-7ca3-49bc-ad78-b8fb91c3f6da'	System	05 Sep 2020 17:05:34
User entered 'None (0)'	System	05 Sep 2020 17:05:34

FDA-CBER-2022-1614-6192072

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:13:54
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:04:13', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '5bfe111e-7ca3-49bc-ad78-b8fb91c3f6da'	System	05 Sep 2020 17:05:34
User entered 'Prevents daily activity and requires medical attention (3)'	System	05 Sep 2020 17:05:34

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-05T12:04:56', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '5bfe111e-7ca3-49bc-ad78-b8fb91c3f6da'	System	05 Sep 2020 17:05:34
User entered 'Yes (Y)'	System	05 Sep 2020 17:05:34

FDA-CBER-2022-1614-6192074

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:13:54
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:05:30', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '5bfe111e-7ca3-49bc-ad78-b8fb91c3f6da'	System	05 Sep 2020 17:05:34
User entered '05 Sep 2020 12:05'	System	05 Sep 2020 17:05:34

FDA-CBER-2022-1614-6192075

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192076

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192077

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 5'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192078

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:13:54
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:45:25', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b9947a8b-06b8-41bb-ad95-01765e74bcc8'	System	07 Sep 2020 00:46:04
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	07 Sep 2020 00:46:04

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:13:54
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:45:29', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b9947a8b-06b8-41bb-ad95-01765e74bcc8'	System	07 Sep 2020 00:46:04
User entered 'No interference with activity (1)'	System	07 Sep 2020 00:46:04

FDA-CBER-2022-1614-6192080

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:13:54
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:45:36', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b9947a8b-06b8-41bb-ad95-01765e74bcc8'	System	07 Sep 2020 00:46:04
User entered 'No interference with activity (1)'	System	07 Sep 2020 00:46:04

FDA-CBER-2022-1614-6192081

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:13:54
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:45:40', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b9947a8b-06b8-41bb-ad95-01765e74bcc8'	System	07 Sep 2020 00:46:04
User entered 'No interference with activity (1)'	System	07 Sep 2020 00:46:04

FDA-CBER-2022-1614-6192082

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:13:54
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:45:43', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b9947a8b-06b8-41bb-ad95-01765e74bcc8'	System	07 Sep 2020 00:46:04
User entered 'None (0)'	System	07 Sep 2020 00:46:04

FDA-CBER-2022-1614-6192083

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:13:54
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:45:50', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b9947a8b-06b8-41bb-ad95-01765e74bcc8'	System	07 Sep 2020 00:46:04
User entered 'No interference with activity (1)'	System	07 Sep 2020 00:46:04

FDA-CBER-2022-1614-6192084

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-06T19:46:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b9947a8b-06b8-41bb-ad95-01765e74bcc8'	System	07 Sep 2020 00:46:04
User entered 'No (N)'	System	07 Sep 2020 00:46:04

FDA-CBER-2022-1614-6192085

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:13:54
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:46:03', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b9947a8b-06b8-41bb-ad95-01765e74bcc8'	System	07 Sep 2020 00:46:04
User entered '06 Sep 2020 19:46'	System	07 Sep 2020 00:46:04

FDA-CBER-2022-1614-6192086

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192087

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192088

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 6'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192089

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:13:54
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:15:46', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '7ab79bb5-a81d-4f1c-ab3d-52fb976c7219'	System	08 Sep 2020 03:16:16
User entered 'No interference with activity (1)'	System	08 Sep 2020 03:16:16

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:13:54
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:15:50', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '7ab79bb5-a81d-4f1c-ab3d-52fb976c7219'	System	08 Sep 2020 03:16:16
User entered 'No interference with activity (1)'	System	08 Sep 2020 03:16:16

FDA-CBER-2022-1614-6192091

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:13:54
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:15:58', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '7ab79bb5-a81d-4f1c-ab3d-52fb976c7219'	System	08 Sep 2020 03:16:16
User entered 'No interference with activity (1)'	System	08 Sep 2020 03:16:16

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:13:54
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:16:02', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '7ab79bb5-a81d-4f1c-ab3d-52fb976c7219'	System	08 Sep 2020 03:16:16
User entered 'No interference with activity (1)'	System	08 Sep 2020 03:16:16

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:13:54
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:16:04', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '7ab79bb5-a81d-4f1c-ab3d-52fb976c7219'	System	08 Sep 2020 03:16:16
User entered 'None (0)'	System	08 Sep 2020 03:16:16

FDA-CBER-2022-1614-6192094

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:13:54
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:16:06', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '7ab79bb5-a81d-4f1c-ab3d-52fb976c7219'	System	08 Sep 2020 03:16:16
User entered 'None (0)'	System	08 Sep 2020 03:16:16

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-07T22:16:09', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '7ab79bb5-a81d-4f1c-ab3d-52fb976c7219'	System	08 Sep 2020 03:16:16
User entered 'No (N)'	System	08 Sep 2020 03:16:16

FDA-CBER-2022-1614-6192096

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:13:54
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:16:12', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '7ab79bb5-a81d-4f1c-ab3d-52fb976c7219'	System	08 Sep 2020 03:16:16
User entered '07 Sep 2020 22:16'	System	08 Sep 2020 03:16:16

FDA-CBER-2022-1614-6192097

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192098

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192099

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 7'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192100

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:13:54
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:57:56', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ca3fe40-6c92-47de-bf84-ca053d5a89d8'	System	09 Sep 2020 02:22:45
User entered 'No interference with activity (1)'	System	09 Sep 2020 02:22:45

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:13:54
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:58:05', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ca3fe40-6c92-47de-bf84-ca053d5a89d8'	System	09 Sep 2020 02:22:45
User entered 'None (0)'	System	09 Sep 2020 02:22:45

FDA-CBER-2022-1614-6192102

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:13:54
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:58:07', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ca3fe40-6c92-47de-bf84-ca053d5a89d8'	System	09 Sep 2020 02:22:45
User entered 'None (0)'	System	09 Sep 2020 02:22:45

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:13:54
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:58:15', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ca3fe40-6c92-47de-bf84-ca053d5a89d8'	System	09 Sep 2020 02:22:45
User entered 'None (0)'	System	09 Sep 2020 02:22:45

FDA-CBER-2022-1614-6192104

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:13:54
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:58:18', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ca3fe40-6c92-47de-bf84-ca053d5a89d8'	System	09 Sep 2020 02:22:45
User entered 'None (0)'	System	09 Sep 2020 02:22:45

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:13:54
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:58:20', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ca3fe40-6c92-47de-bf84-ca053d5a89d8'	System	09 Sep 2020 02:22:45
User entered 'None (0)'	System	09 Sep 2020 02:22:45

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-08T20:58:35', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ca3fe40-6c92-47de-bf84-ca053d5a89d8'	System	09 Sep 2020 02:22:45
User entered 'No (N)'	System	09 Sep 2020 02:22:45

FDA-CBER-2022-1614-6192107

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:13:54
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:58:39', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ca3fe40-6c92-47de-bf84-ca053d5a89d8'	System	09 Sep 2020 02:22:45
User entered '08 Sep 2020 20:58'	System	09 Sep 2020 02:22:45

FDA-CBER-2022-1614-6192108

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192109

US3752366
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192110

US3752366
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 03:16:16
User entered 'Day 8'	System	08 Sep 2020 03:16:16

FDA-CBER-2022-1614-6192111

US3752366
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 26 Nov 2020 11:13:54
Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-09T16:37:42', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd36ff91d-de8b-489d-8be6-7acb0d525c5f'	System	09 Sep 2020 21:37:51
User entered 'None (0)'	System	09 Sep 2020 21:37:51

US3752366
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 26 Nov 2020 11:13:54
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-09T16:37:45', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd36ff91d-de8b-489d-8be6-7acb0d525c5f'	System	09 Sep 2020 21:37:51
User entered '09 Sep 2020 16:37'	System	09 Sep 2020 21:37:51

FDA-CBER-2022-1614-6192113

US3752366
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 03:16:16

FDA-CBER-2022-1614-6192114

US3752366
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 03:16:16

US3752366
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 03:16:16
User entered 'Day 8'	System	08 Sep 2020 03:16:16

FDA-CBER-2022-1614-6192116

US3752366
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 26 Nov 2020 11:13:54
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 (0a7df3d2377246f6)', Time: '2020-09-09T16:37:51', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '0c7f1066-fa15-4ba6-83e9-51ab2022a87f'	System	09 Sep 2020 21:37:57
User entered 'No (N)'	System	09 Sep 2020 21:37:57

FDA-CBER-2022-1614-6192117

US3752366
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 26 Nov 2020 11:13:54
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-09T16:37:53', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '0c7f1066-fa15-4ba6-83e9-51ab2022a87f'	System	09 Sep 2020 21:37:57
User entered '09 Sep 2020 16:37'	System	09 Sep 2020 21:37:57

US3752366
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 26 Nov 2020 11:13:54
PC Open Date & Time

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 03:16:16

FDA-CBER-2022-1614-6192119

US3752366
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 26 Nov 2020 11:13:54
PC Close Date & Time

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 03:16:16

FDA-CBER-2022-1614-6192120

US3752366
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 19:28:44

FDA-CBER-2022-1614-6192121

US3752366
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '9 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 19:28:44

FDA-CBER-2022-1614-6192122

US3752366
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Sep 2020 19:28:44

FDA-CBER-2022-1614-6192123

US3752366
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 19:28:44

FDA-CBER-2022-1614-6192124

US3752366
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:13:54
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 19:30:46

FDA-CBER-2022-1614-6192125

US3752366
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:13:54
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 19:30:46

FDA-CBER-2022-1614-6192126

US3752366
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 19:31:07

FDA-CBER-2022-1614-6192127

US3752366
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 19:31:07

FDA-CBER-2022-1614-6192128

US3752366
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Sep 2020 19:31:07

FDA-CBER-2022-1614-6192129

US3752366
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 19:31:07

FDA-CBER-2022-1614-6192130

US3752366
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:13:54
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 19:31:42

FDA-CBER-2022-1614-6192131

US3752366
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:13:54
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 19:31:42

FDA-CBER-2022-1614-6192132

US3752366
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 19:32:00

FDA-CBER-2022-1614-6192133

US3752366
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '23 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 19:32:00

FDA-CBER-2022-1614-6192134

US3752366
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Sep 2020 19:32:00

FDA-CBER-2022-1614-6192135

US3752366
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 19:32:00

FDA-CBER-2022-1614-6192136

US3752366
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:13:54
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 19:38:55

FDA-CBER-2022-1614-6192137

US3752366
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:13:54
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:38:55

FDA-CBER-2022-1614-6192138

US3752366
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Was this visit performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 19:48:54

FDA-CBER-2022-1614-6192139

US3752366
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 19:48:54

FDA-CBER-2022-1614-6192140

US3752366
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	07 Oct 2020 19:48:54

FDA-CBER-2022-1614-6192141

US3752366
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Folder OID

Audit	User	Time (GMT)
User entered 'VISIT2'	System	07 Oct 2020 19:48:54

FDA-CBER-2022-1614-6192142

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192143

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192144

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '07 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192145

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '13:20'	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192146

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '07 Oct 2020 13:20'	System	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192147

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User entered '98.2' F	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192148

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Route of measurement

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192149

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
If Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192150

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Pulse *(xxx)*

Audit	User	Time (GMT)
User entered '76'	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192151

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192152

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192153

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192154

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '114'	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192155

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192156

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '76'	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192157

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 11:13:54
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192158

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192159

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192160

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192161

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192162

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192163

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192164

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Route of measurement

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192165

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
If Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192166

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Pulse *(xxx)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192167

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Pulse units

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192168

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192169

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Respiratory Rate units

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192170

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192171

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192172

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192173

US3752366
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 11:13:54
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:50:00

FDA-CBER-2022-1614-6192174

US3752366
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:13:54
Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 19:50:11

FDA-CBER-2022-1614-6192175

US3752366
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:13:54
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '07 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 19:50:11

FDA-CBER-2022-1614-6192176

US3752366
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:13:54
Was study treatment given?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 19:50:20

FDA-CBER-2022-1614-6192177

US3752366
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:13:54
If No, reason not given

Audit	User	Time (GMT)
User closed query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	07 Oct 2020 19:51:05
User entered 'Confirmed COVID-19 (COVID)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:51:05
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	07 Oct 2020 19:50:20
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:50:20

FDA-CBER-2022-1614-6192178

US3752366
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:13:54
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:50:20

FDA-CBER-2022-1614-6192179

US3752366
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:13:54
What was the study treatment?

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:50:20

FDA-CBER-2022-1614-6192180

US3752366
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:13:54
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:50:20

US3752366
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:13:54
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:50:20

FDA-CBER-2022-1614-6192182

US3752366
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:13:54
Treatment Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:50:20

FDA-CBER-2022-1614-6192183

US3752366
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:13:54
Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:50:20

FDA-CBER-2022-1614-6192184

US3752366
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:13:54
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:50:20

FDA-CBER-2022-1614-6192185

US3752366
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 11:13:54
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:50:20

FDA-CBER-2022-1614-6192186

US3752366
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:13:54
Was the sample collected?

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 2 Day 29 with a Collection Date of 07OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:53:56
Query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 2 Day 29 with a Collection Date of 07OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate.' answered with 'Date is correct. Sample collected visit 2 day 29' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:22:38
User opened query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 2 Day 29 with a Collection Date of 07OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:30:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 19:51:28

FDA-CBER-2022-1614-6192187

US3752366
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:13:54
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '07 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 19:51:28

FDA-CBER-2022-1614-6192188

US3752366
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:13:54
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '13:47'	(b) (4), (b) (6)	07 Oct 2020 19:51:28

FDA-CBER-2022-1614-6192189

US3752366
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:13:54
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '07 Oct 2020 13:47'	System	07 Oct 2020 19:51:28

FDA-CBER-2022-1614-6192190

US3752366
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 26 Nov 2020 11:13:54
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation re-query: Swab: response noted. Please confirm if an unscheduled lab kit was used for visit 2 day 2. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 14:13:21
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 07OCT2020is recorded under Visit 2 Day 29 in EDC; however, the same is reported under “Unscheduled” visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 14:13:21
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 07OCT2020is recorded under Visit 2 Day 29 in EDC; however, the same is reported under “Unscheduled” visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' answered with 'Sample was collected on 07OCT2020' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 18:15:50
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 07OCT2020is recorded under Visit 2 Day 29 in EDC; however, the same is reported under “Unscheduled” visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:38:27
User entered '07 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 19:51:46

FDA-CBER-2022-1614-6192191

US3752366
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 11:13:54
Lab Test

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	07 Oct 2020 19:51:46

FDA-CBER-2022-1614-6192192

US3752366
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 11:13:54
Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 19:51:46

FDA-CBER-2022-1614-6192193

US3752366
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 11:13:54
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
User entered '13:52'	(b) (4), (b) (6)	07 Oct 2020 19:51:46

FDA-CBER-2022-1614-6192194

US3752366
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 11:13:54
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '07 Oct 2020 13:52'	System	07 Oct 2020 19:51:46

US3752366
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 11:13:54
Lab Test

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	07 Oct 2020 19:51:46

FDA-CBER-2022-1614-6192196

US3752366
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 11:13:54
Was the sample collected?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 19:51:46

FDA-CBER-2022-1614-6192197

US3752366
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 11:13:54
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:51:46

FDA-CBER-2022-1614-6192198

US3752366
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 11:13:54
Collection date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:51:46

FDA-CBER-2022-1614-6192199

US3752366
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:13:54
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 19:51:51

FDA-CBER-2022-1614-6192200

US3752366
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:13:54
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:51:51

FDA-CBER-2022-1614-6192201

US3752366
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 21:33:23

FDA-CBER-2022-1614-6192202

US3752366
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 21:33:23

FDA-CBER-2022-1614-6192203

US3752366
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 21:33:23

FDA-CBER-2022-1614-6192204

US3752366
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 21:33:23

FDA-CBER-2022-1614-6192205

US3752366
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:13:54
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 21:33:29

FDA-CBER-2022-1614-6192206

US3752366
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:13:54
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 21:33:29

FDA-CBER-2022-1614-6192207

US3752366
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	23 Oct 2020 12:50:19

FDA-CBER-2022-1614-6192208

US3752366
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Amanda Horn (b) (4) (b) (4)	23 Oct 2020 12:50:19

FDA-CBER-2022-1614-6192209

US3752366
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	23 Oct 2020 12:50:19

FDA-CBER-2022-1614-6192210

US3752366
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 11:13:54
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Oct 2020 12:50:19

FDA-CBER-2022-1614-6192211

US3752366
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:13:54
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 16:36:27

FDA-CBER-2022-1614-6192212

US3752366
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:13:54
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 16:36:27

FDA-CBER-2022-1614-6192213

US3752366
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:13:54
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 16:36:36

FDA-CBER-2022-1614-6192214

US3752366
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:13:54
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 16:36:36

FDA-CBER-2022-1614-6192215

US3752366
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Was this visit performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 16:36:50

FDA-CBER-2022-1614-6192216

US3752366
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '04 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 16:36:50

FDA-CBER-2022-1614-6192217

US3752366
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Nov 2020 16:36:50

FDA-CBER-2022-1614-6192218

US3752366
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Folder OID

Audit	User	Time (GMT)
User entered 'VISIT3'	System	05 Nov 2020 16:36:50

FDA-CBER-2022-1614-6192219

US3752366
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 16:37:25

FDA-CBER-2022-1614-6192220

US3752366
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '04 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 16:37:25

FDA-CBER-2022-1614-6192221

US3752366
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '12:40'	(b) (4), (b) (6)	05 Nov 2020 16:37:25

FDA-CBER-2022-1614-6192222

US3752366
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '04 Nov 2020 12:40'	System	05 Nov 2020 16:37:25

FDA-CBER-2022-1614-6192223

US3752366
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User entered '98.7' F	(b) (4), (b) (6)	05 Nov 2020 16:37:25

FDA-CBER-2022-1614-6192224

US3752366
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Route of measurement

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	05 Nov 2020 16:37:25

FDA-CBER-2022-1614-6192225

US3752366
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
If Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:37:25

FDA-CBER-2022-1614-6192226

US3752366
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Pulse *(xxx)*

Audit	User	Time (GMT)
User entered '73'	(b) (4), (b) (6)	05 Nov 2020 16:37:25

FDA-CBER-2022-1614-6192227

US3752366
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Nov 2020 16:37:25

FDA-CBER-2022-1614-6192228

US3752366
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	05 Nov 2020 16:37:25

FDA-CBER-2022-1614-6192229

US3752366
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Nov 2020 16:37:25

FDA-CBER-2022-1614-6192230

US3752366
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '124'	(b) (4), (b) (6)	05 Nov 2020 16:37:25

FDA-CBER-2022-1614-6192231

US3752366
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 16:37:25

FDA-CBER-2022-1614-6192232

US3752366
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '86'	(b) (4), (b) (6)	05 Nov 2020 16:37:25

FDA-CBER-2022-1614-6192233

US3752366
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 16:37:25

FDA-CBER-2022-1614-6192234

US3752366
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:13:54
Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 16:37:33

FDA-CBER-2022-1614-6192235

US3752366
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:13:54
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '04 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 16:37:33

FDA-CBER-2022-1614-6192236

US3752366
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:13:54
Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 16:37:52

FDA-CBER-2022-1614-6192237

US3752366
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:13:54
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '04 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 16:37:52

FDA-CBER-2022-1614-6192238

US3752366
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:13:54
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '12:52'	(b) (4), (b) (6)	05 Nov 2020 16:37:52

FDA-CBER-2022-1614-6192239

US3752366
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 11:13:54
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '04 Nov 2020 12:52'	System	05 Nov 2020 16:37:52

FDA-CBER-2022-1614-6192240

US3752366
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:13:54
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 16:38:04

FDA-CBER-2022-1614-6192241

US3752366
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 26 Nov 2020 11:13:54
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 16:38:04

FDA-CBER-2022-1614-6192242

US3752366
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 64'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192243

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:54

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 (0a7df3d2377246f6)', Time: '2020-11-06T00:13:06', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'bd2f8369-3fc3-4dc2-bfa4-362332844b88'	System	06 Nov 2020 06:13:29
User entered 'No (N)'	System	06 Nov 2020 06:13:29

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:54

Have you been exposed to someone with 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 (0a7df3d2377246f6)', Time: '2020-11-06T00:13:19', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'bd2f8369-3fc3-4dc2-bfa4-362332844b88'	System	06 Nov 2020 06:13:29
User entered 'No (N)'	System	06 Nov 2020 06:13:29

US3752366
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-11-06T00:13:25', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'bd2f8369-3fc3-4dc2-bfa4-362332844b88'	System	06 Nov 2020 06:13:29
User entered '06 Nov 2020 00:13:25'	System	06 Nov 2020 06:13:29

US3752366
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192247

US3752366
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192248

US3752366
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 71'	System	02 Sep 2020 19:31:46

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:54

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 (0a7df3d2377246f6)', Time: '2020-11-11T06:43:10', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'e61f19ac-20da-49ff-9f00-ec987177c6aa'	System	11 Nov 2020 12:43:33
User entered 'No (N)'	System	11 Nov 2020 12:43:33

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:54

Have you been exposed to someone with 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 (0a7df3d2377246f6)', Time: '2020-11-11T06:43:25', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'e61f19ac-20da-49ff-9f00-ec987177c6aa'	System	11 Nov 2020 12:43:33
User entered 'No (N)'	System	11 Nov 2020 12:43:33

US3752366
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-11-11T06:43:30', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'e61f19ac-20da-49ff-9f00-ec987177c6aa'	System	11 Nov 2020 12:43:33
User entered '11 Nov 2020 06:43:30'	System	11 Nov 2020 12:43:33

FDA-CBER-2022-1614-6192252

US3752366
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192253

US3752366
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192254

US3752366
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 78'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192255

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:54

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 (0a7df3d2377246f6)', Time: '2020-11-19T07:50:18', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ce76820-6bd6-4743-9984-51855a273bb6'	System	19 Nov 2020 13:50:51
User entered 'No (N)'	System	19 Nov 2020 13:50:51

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:54

Have you been exposed to someone with 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 (0a7df3d2377246f6)', Time: '2020-11-19T07:50:41', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ce76820-6bd6-4743-9984-51855a273bb6'	System	19 Nov 2020 13:50:51
User entered 'No (N)'	System	19 Nov 2020 13:50:51

US3752366
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-11-19T07:50:46', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ce76820-6bd6-4743-9984-51855a273bb6'	System	19 Nov 2020 13:50:51
User entered '19 Nov 2020 07:50:46'	System	19 Nov 2020 13:50:51

US3752366
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 19:31:46

US3752366
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:31:46
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 19:31:46

FDA-CBER-2022-1614-6192260

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192261

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '30 Oct 2020 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192262

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '03 Nov 2020 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192263

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192264

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '06 Nov 2020 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192265

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '10 Nov 2020 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192266

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192267

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '13 Nov 2020 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192268

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '17 Nov 2020 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192269

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192270

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192271

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192272

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192273

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192274

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192275

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192276

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192277

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192278

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192279

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192280

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192281

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192282

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192283

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192284

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192285

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192286

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192287

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192288

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192289

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192290

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192291

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192292

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192293

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192294

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192295

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192296

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192297

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192298

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192299

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192300

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192301

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192302

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192303

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192304

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192305

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192306

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192307

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192308

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192309

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192310

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192311

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192312

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192313

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192314

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192315

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192316

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192317

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192318

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192319

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192320

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192321

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192322

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192323

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192324

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192325

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192326

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192327

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192328

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192329

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192330

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192331

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192332

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192333

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192334

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192335

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192336

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192337

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192338

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192339

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192340

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192341

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192342

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192343

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192344

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192345

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192346

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192347

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192348

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192349

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192350

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192351

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192352

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192353

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192354

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192355

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192356

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192357

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192358

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192359

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192360

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192361

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192362

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192363

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192364

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192365

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192366

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192367

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192368

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192369

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192370

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192371

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192372

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192373

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192374

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192375

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192376

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192377

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192378

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192379

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192380

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:49:03

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192382

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192384

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192385

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192386

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:49:03

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192388

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192389

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192390

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192391

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192392

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192393

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192394

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192395

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192396

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192397

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192398

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192399

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192400

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192401

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192402

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192403

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192404

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192405

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192406

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192407

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192408

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192409

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192410

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192411

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192412

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192413

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192414

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192415

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192416

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192417

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192418

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192419

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192420

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192421

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192422

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192423

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192424

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192425

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192426

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192427

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192428

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192429

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192430

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192431

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:49:03

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192433

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192434

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192435

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192436

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192437

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192438

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192439

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192440

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192441

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192442

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192443

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192444

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192445

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192446

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192447

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192448

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192449

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192450

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192451

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192452

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192453

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192454

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192455

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192456

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192457

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192458

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192459

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192460

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192461

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192462

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192463

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192464

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192465

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192466

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192467

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192468

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192469

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192470

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192471

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192472

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192473

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192474

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192475

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192476

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192477

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192478

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192479

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192480

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192481

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192483

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192484

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192485

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192486

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192487

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192488

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192489

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192490

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192491

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192492

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192493

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192494

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192495

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192496

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192497

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192498

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192499

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192500

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192501

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192502

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192504

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192505

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192506

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192507

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192508

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192509

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192510

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192511

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192512

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192513

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192514

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192515

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192516

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192517

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192518

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192519

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192520

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192521

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192522

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192524

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192525

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192526

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192528

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192529

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192530

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192531

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192532

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192533

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192534

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192535

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192536

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192537

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192538

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192539

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192540

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192541

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192542

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192543

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192544

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192546

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192547

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192549

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192550

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192551

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192552

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192553

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192554

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192555

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192557

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192558

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192559

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192560

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192561

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192562

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192563

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192564

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192565

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192566

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192567

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192568

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192569

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192570

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192571

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192572

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192573

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192574

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192575

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192576

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 11:13:54
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:49:03

FDA-CBER-2022-1614-6192578

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: COVID-19 Contact
Generated On: 26 Nov 2020 11:13:54
Date of Contact

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:09:58
User entered '6 Sep 2020'	(b) (4), (b) (6)	07 Sep 2020 00:59:55

FDA-CBER-2022-1614-6192579

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: COVID-19 Contact
Generated On: 26 Nov 2020 11:13:54
Time of Contact

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 02:37:41
User closed query 'Per source time of contact is noted as "1745"please verify and update EDC. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 02:37:39
Query 'Per source time of contact is noted as "1745"please verify and update EDC. ' answered by data change (Site from CRA).	System	11 Nov 2020 20:24:39
User entered '17:45' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 20:24:39
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:10:02
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:09:58
User opened query 'Per source time of contact is noted as "1745"please verify and update EDC. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:09:40
User entered '13:27'	(b) (4), (b) (6)	07 Sep 2020 00:59:55

FDA-CBER-2022-1614-6192580

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: COVID-19 Contact
Generated On: 26 Nov 2020 11:13:54
Date and Time of Contact (derived)

Audit	User	Time (GMT)
User entered '6 Sep 2020 17:45'	System	11 Nov 2020 20:24:39
User entered '6 Sep 2020 13:27'	System	07 Sep 2020 00:59:55

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: COVID-19 Contact
Generated On: 26 Nov 2020 11:13:54
Type of Contact

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:09:58
User entered 'Safety Call (Safety Call)'	(b) (4), (b) (6)	07 Sep 2020 00:59:55

FDA-CBER-2022-1614-6192582

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: COVID-19 Contact
Generated On: 26 Nov 2020 11:13:54
Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:09:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Sep 2020 00:59:55

FDA-CBER-2022-1614-6192583

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
Symptom Day

Audit	User	Time (GMT)
User closed query 'Per CDM: it appears that Day 1 is missing and Day 2 date of 09SEP2020 is after Contact Date of 06SEP2020. Please reconcile' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 23:32:58
User closed query 'Subject's 1 day of symptoms started on 04Sep2020.Please verify and update EDC. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 02:37:53
Query 'Per CDM: it appears that Day 1 is missing and Day 2 date of 09SEP2020 is after Contact Date of 06SEP2020. Please reconcile' answered with 'RECONCILED' (Site from DM).	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:18:14
Query 'Subject's 1 day of symptoms started on 04Sep2020.Please verify and update EDC. ' answered by data change (Site from CRA).	System	10 Nov 2020 22:02:40
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
User opened query 'Subject's 1 day of symptoms started on 04Sep2020.Please verify and update EDC. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:29:56
User opened query 'Per CDM: it appears that Day 1 is missing and Day 2 date of 09SEP2020 is after Contact Date of 06SEP2020. Please reconcile' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:19:44
User entered 'Day 2 (Day 2)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192584

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
Date

Audit	User	Time (GMT)
User entered '4 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '9 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192585

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
Assessment Not Done

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192586

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '100'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192587

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192588

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
Temperature

Audit	User	Time (GMT)
User entered '99.6' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:43:39
User entered '098.1' F	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192589

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
Chills

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192590

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
Cough

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192591

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
Shortness of Breath

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192592

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
Difficulty Breathing

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192593

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
Fatigue

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192594

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192595

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
Body Aches

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192596

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
Headache

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192597

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
New Loss of Taste

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192598

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
New Loss of Smell

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192599

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
Nasal Congestion

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192600

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192601

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
Nausea

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192602

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
Vomiting

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192603

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
Diarrhea

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192604

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (1)
Generated On: 26 Nov 2020 11:13:54
Sore Throat

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

FDA-CBER-2022-1614-6192605

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
User entered 'Day 3 (Day 3)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192606

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
Date

Audit	User	Time (GMT)
User entered '5 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '10 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192607

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
Assessment Not Done

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192608

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:17:20
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '100'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192609

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192610

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
Temperature

Audit	User	Time (GMT)
User entered '101.6' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:17:20
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '99.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:43:54
User entered '099.0' F	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
Chills

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192612

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
Cough

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:17:20
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192613

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
Shortness of Breath

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192614

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
Difficulty Breathing

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192615

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
Fatigue

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192616

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192617

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
Body Aches

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192618

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
Headache

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:17:20
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192619

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
New Loss of Taste

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192620

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
New Loss of Smell

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192621

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
Nasal Congestion

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192622

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 22:59:51
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:17:20
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192623

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
Nausea

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192624

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
Vomiting

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192625

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
Diarrhea

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:17:20
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192626

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (2)
Generated On: 26 Nov 2020 11:13:54
Sore Throat

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

FDA-CBER-2022-1614-6192627

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
User entered 'Day 4 (Day 4)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192628

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
Date

Audit	User	Time (GMT)
User entered '6 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '11 Sep 2020'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192629

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
Assessment Not Done

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192630

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '100'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192631

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation Units

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 23:00:48
User entered '%'	System	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192632

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
Temperature

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '98.2' F	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192633

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
Chills

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192634

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
Cough

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192635

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
Shortness of Breath

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192636

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
Difficulty Breathing

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192637

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
Fatigue

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192638

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192639

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
Body Aches

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192640

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
Headache

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192641

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
New Loss of Taste

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Severe (Severe)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192642

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
New Loss of Smell

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Severe (Severe)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192643

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
Nasal Congestion

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192644

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192645

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
Nausea

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192646

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
Vomiting

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192647

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
Diarrhea

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192648

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (3)
Generated On: 26 Nov 2020 11:13:54
Sore Throat

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

FDA-CBER-2022-1614-6192649

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
User entered 'Day 5 (Day 5)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
Date

Audit	User	Time (GMT)
User entered '7 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '12 Sep 2020'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192651

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
Assessment Not Done

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192652

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '99'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192653

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation Units

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 23:01:51
User entered '%'	System	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192654

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
Temperature

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '98.2' F	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192655

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
Chills

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192656

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
Cough

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192657

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
Shortness of Breath

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192658

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
Difficulty Breathing

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192659

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
Fatigue

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192660

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192661

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
Body Aches

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192662

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
Headache

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192663

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
New Loss of Taste

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192664

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
New Loss of Smell

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192665

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
Nasal Congestion

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192666

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192667

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
Nausea

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192668

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
Vomiting

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192669

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
Diarrhea

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192670

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (4)
Generated On: 26 Nov 2020 11:13:54
Sore Throat

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192671

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
User entered 'Day 6 (Day 6)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192672

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
Date

Audit	User	Time (GMT)
User entered '8 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '13 Sep 2020'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192673

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
Assessment Not Done

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192674

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '100'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192675

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192676

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
Temperature

Audit	User	Time (GMT)
User entered '98.2' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '99.7' F	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192677

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
Chills

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192678

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
Cough

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192679

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
Shortness of Breath

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192680

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
Difficulty Breathing

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192681

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
Fatigue

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192682

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192683

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
Body Aches

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192684

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
Headache

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192685

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
New Loss of Taste

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192686

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
New Loss of Smell

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192687

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
Nasal Congestion

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192688

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192689

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
Nausea

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192690

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
Vomiting

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192691

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
Diarrhea

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192692

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (5)
Generated On: 26 Nov 2020 11:13:54
Sore Throat

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192693

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
User entered 'Day 7 (Day 7)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192694

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
Date

Audit	User	Time (GMT)
User entered '9 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '14 Sep 2020'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192695

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
Assessment Not Done

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192696

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '100'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192697

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192698

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
Temperature

Audit	User	Time (GMT)
User entered '98.1' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:06:03
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '98.7' F	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192699

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
Chills

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192700

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
Cough

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192701

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
Shortness of Breath

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192702

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
Difficulty Breathing

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192703

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
Fatigue

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192704

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192705

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
Body Aches

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192706

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
Headache

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192707

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
New Loss of Taste

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192708

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
New Loss of Smell

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192709

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
Nasal Congestion

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192710

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192711

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
Nausea

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192712

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
Vomiting

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192713

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
Diarrhea

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:06:03
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192714

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (6)
Generated On: 26 Nov 2020 11:13:54
Sore Throat

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

FDA-CBER-2022-1614-6192715

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
User entered 'Day 8 (Day 8)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192716

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
Date

Audit	User	Time (GMT)
User entered '10 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '15 Sep 2020'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192717

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
Assessment Not Done

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192718

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '100'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192719

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192720

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
Temperature

Audit	User	Time (GMT)
User entered '99.0' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:06:50
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '98.4' F	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192721

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
Chills

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192722

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
Cough

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:06:50
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192723

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
Shortness of Breath

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192724

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
Difficulty Breathing

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192725

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
Fatigue

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192726

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192727

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
Body Aches

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192728

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
Headache

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192729

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
New Loss of Taste

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192730

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
New Loss of Smell

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192731

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
Nasal Congestion

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192732

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:06:50
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192733

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
Nausea

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192734

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
Vomiting

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192735

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
Diarrhea

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192736

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (7)
Generated On: 26 Nov 2020 11:13:54
Sore Throat

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

FDA-CBER-2022-1614-6192737

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
User entered 'Day 9 (Day 9)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192738

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
Date

Audit	User	Time (GMT)
User entered '11 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '16 Sep 2020'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192739

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
Assessment Not Done

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192740

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '100'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192741

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192742

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
Temperature

Audit	User	Time (GMT)
User entered '98.2' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:07:42
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:44:36
User entered '098.1' F	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192743

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
Chills

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192744

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
Cough

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:07:42
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192745

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
Shortness of Breath

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192746

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
Difficulty Breathing

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192747

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
Fatigue

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192748

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192749

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
Body Aches

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192750

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
Headache

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192751

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
New Loss of Taste

Audit	User	Time (GMT)
User entered 'Severe (Severe)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:07:42
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192752

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
New Loss of Smell

Audit	User	Time (GMT)
User entered 'Severe (Severe)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:07:42
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192753

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
Nasal Congestion

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192754

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:07:42
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192755

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
Nausea

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192756

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
Vomiting

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192757

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
Diarrhea

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192758

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (8)
Generated On: 26 Nov 2020 11:13:54
Sore Throat

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

FDA-CBER-2022-1614-6192759

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
User entered 'Day 10 (Day 10)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

FDA-CBER-2022-1614-6192760

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
Date

Audit	User	Time (GMT)
User entered '12 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '17 Sep 2020'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

FDA-CBER-2022-1614-6192761

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
Assessment Not Done

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

FDA-CBER-2022-1614-6192762

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '99'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

FDA-CBER-2022-1614-6192763

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	21 Sep 2020 15:01:47

FDA-CBER-2022-1614-6192764

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
Temperature

Audit	User	Time (GMT)
User entered '98.2' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:09:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '97.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:44:48
User entered '097.2' F	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
Chills

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

FDA-CBER-2022-1614-6192766

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
Cough

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:09:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

FDA-CBER-2022-1614-6192767

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
Shortness of Breath

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

FDA-CBER-2022-1614-6192768

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
Difficulty Breathing

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

FDA-CBER-2022-1614-6192769

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
Fatigue

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

FDA-CBER-2022-1614-6192770

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

FDA-CBER-2022-1614-6192771

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
Body Aches

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

FDA-CBER-2022-1614-6192772

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
Headache

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
New Loss of Taste

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

FDA-CBER-2022-1614-6192774

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
New Loss of Smell

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:09:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

FDA-CBER-2022-1614-6192775

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
Nasal Congestion

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:09:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

FDA-CBER-2022-1614-6192776

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

FDA-CBER-2022-1614-6192777

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
Nausea

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

FDA-CBER-2022-1614-6192778

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
Vomiting

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

FDA-CBER-2022-1614-6192779

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
Diarrhea

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:09:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

FDA-CBER-2022-1614-6192780

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (9)
Generated On: 26 Nov 2020 11:13:54
Sore Throat

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

FDA-CBER-2022-1614-6192781

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
User entered 'Day 11 (Day 11)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192782

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
Date

Audit	User	Time (GMT)
User entered '13 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '18 Sep 2020'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192783

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
Assessment Not Done

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192784

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation

Audit	User	Time (GMT)
User entered '100' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:10:18
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '98'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192785

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192786

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
Temperature

Audit	User	Time (GMT)
User entered '99.7' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:10:18
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '97.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:44:59
User entered '097.9' F	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
Chills

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192788

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
Cough

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:10:18
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192789

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
Shortness of Breath

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192790

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
Difficulty Breathing

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192791

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
Fatigue

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192792

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192793

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
Body Aches

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192794

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
Headache

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192795

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
New Loss of Taste

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:10:18
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192796

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
New Loss of Smell

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:10:18
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192797

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
Nasal Congestion

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192798

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192799

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
Nausea

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192800

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
Vomiting

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192801

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
Diarrhea

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192802

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (10)
Generated On: 26 Nov 2020 11:13:54
Sore Throat

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

FDA-CBER-2022-1614-6192803

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:36
User entered 'Day 12 (Day 12)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192804

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
Date

Audit	User	Time (GMT)
User entered '14 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '19 Sep 2020'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192805

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
Assessment Not Done

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192806

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation

Audit	User	Time (GMT)
User entered '100' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:10:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '99'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192807

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192808

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
Temperature

Audit	User	Time (GMT)
User entered '98.3' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:10:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '97.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:45:14
User entered '097.0' F	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
Chills

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192810

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
Cough

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:10:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192811

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
Shortness of Breath

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192812

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
Difficulty Breathing

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192813

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
Fatigue

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192814

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192815

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
Body Aches

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192816

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
Headache

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192817

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
New Loss of Taste

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192818

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
New Loss of Smell

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192819

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
Nasal Congestion

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192820

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192821

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
Nausea

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192822

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
Vomiting

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192823

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
Diarrhea

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192824

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (11)
Generated On: 26 Nov 2020 11:13:54
Sore Throat

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

FDA-CBER-2022-1614-6192825

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:36
User entered 'Day 13 (Day 13)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192826

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
Date

Audit	User	Time (GMT)
User entered '15 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '20 Sep 2020'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192827

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
Assessment Not Done

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192828

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation

Audit	User	Time (GMT)
User entered '100' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '98'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192829

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192830

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
Temperature

Audit	User	Time (GMT)
User entered '98.4' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '97.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:45:28
User entered '097.2' F	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192831

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
Chills

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192832

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
Cough

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192833

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
Shortness of Breath

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192834

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
Difficulty Breathing

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192835

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
Fatigue

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192836

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192837

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
Body Aches

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192838

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
Headache

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192839

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
New Loss of Taste

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192840

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
New Loss of Smell

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192841

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
Nasal Congestion

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192842

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192843

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
Nausea

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192844

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
Vomiting

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192845

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
Diarrhea

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192846

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (12)
Generated On: 26 Nov 2020 11:13:54
Sore Throat

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

FDA-CBER-2022-1614-6192847

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:36
User entered 'Day 14 (Day 14)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192848

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
Date

Audit	User	Time (GMT)
User entered '16 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
Query 'Per CDM: it appears additional records may be missing as there is a Convalescence Visit Day 28 recorded with date of 07OCT2020. Please reconcile' canceled (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:21:01
User opened query 'Per CDM: it appears additional records may be missing as there is a Convalescence Visit Day 28 recorded with date of 07OCT2020. Please reconcile' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:21:05
User entered '21 Sep 2020'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192849

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
Assessment Not Done

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192850

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation

Audit	User	Time (GMT)
User entered '100' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:13:49
User entered '99' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:12:57
User entered '100' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:12:32
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '99'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192851

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192852

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
Temperature

Audit	User	Time (GMT)
User entered '98.1' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:13:49
User entered '97.2' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:12:57
User entered '98.1' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:12:32
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '97.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:45:49
User entered '097.2' F	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
Chills

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192854

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
Cough

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192855

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
Shortness of Breath

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192856

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
Difficulty Breathing

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192857

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
Fatigue

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192858

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192859

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
Body Aches

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192860

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
Headache

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192861

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
New Loss of Taste

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192862

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
New Loss of Smell

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192863

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
Nasal Congestion

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192864

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192865

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
Nausea

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192866

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
Vomiting

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192867

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
Diarrhea

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192868

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (13)
Generated On: 26 Nov 2020 11:13:54
Sore Throat

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192869

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:36
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192870

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
Date

Audit	User	Time (GMT)
User entered '17 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 09:52:06
Query 'Data is required. Please complete.' answered with 'DATA ENTRY ERROR. NO FURTHER ASSESSMENTS COMPLETED DUE TO SYMPTOM RESOLUTION' (Site from System).	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:47:23
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 16:46:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192871

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
Assessment Not Done

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192872

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation

Audit	User	Time (GMT)
User entered '99' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192873

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	11 Nov 2020 23:14:31
User entered empty.	System	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192874

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
Temperature

Audit	User	Time (GMT)
User entered '97.2' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192875

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
Chills

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192876

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
Cough

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192877

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
Shortness of Breath

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192878

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
Difficulty Breathing

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192879

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
Fatigue

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192880

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192881

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
Body Aches

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192882

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
Headache

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192883

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
New Loss of Taste

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192884

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
New Loss of Smell

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192885

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
Nasal Congestion

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192886

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192887

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
Nausea

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192888

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
Vomiting

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192889

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
Diarrhea

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192890

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (14)
Generated On: 26 Nov 2020 11:13:54
Sore Throat

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

FDA-CBER-2022-1614-6192891

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)'	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192892

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
Date

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192893

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
Assessment Not Done

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192894

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation

Audit	User	Time (GMT)
User entered '98' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192895

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	11 Nov 2020 23:15:26
User entered empty.	System	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192896

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
Temperature

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Nov 2020 23:15:45
User entered '97.9' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Nov 2020 23:15:26
User entered '97.9' (non-conformant).	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192897

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
Chills

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192898

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
Cough

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192899

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
Shortness of Breath

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192900

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
Difficulty Breathing

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192901

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
Fatigue

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192902

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192903

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
Body Aches

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192904

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
Headache

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192905

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
New Loss of Taste

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192906

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
New Loss of Smell

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192907

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
Nasal Congestion

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192908

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192909

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
Nausea

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192910

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
Vomiting

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192911

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
Diarrhea

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192912

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (15)
Generated On: 26 Nov 2020 11:13:54
Sore Throat

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

FDA-CBER-2022-1614-6192913

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)'	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192914

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
Date

Audit	User	Time (GMT)
User entered '19 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192915

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
Assessment Not Done

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192916

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation

Audit	User	Time (GMT)
User entered '99' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192917

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	11 Nov 2020 23:16:29
User entered empty.	System	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192918

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
Temperature

Audit	User	Time (GMT)
User entered '97.0' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192919

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
Chills

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192920

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
Cough

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192921

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
Shortness of Breath

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192922

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
Difficulty Breathing

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192923

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
Fatigue

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192924

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192925

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
Body Aches

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192926

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
Headache

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192927

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
New Loss of Taste

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192928

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
New Loss of Smell

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192929

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
Nasal Congestion

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192930

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192931

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
Nausea

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192932

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
Vomiting

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192933

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
Diarrhea

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192934

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (16)
Generated On: 26 Nov 2020 11:13:54
Sore Throat

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

FDA-CBER-2022-1614-6192935

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 17 (Day 17)'	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192936

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
Date

Audit	User	Time (GMT)
User entered '20 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192937

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
Assessment Not Done

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192938

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation

Audit	User	Time (GMT)
User entered '98' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192939

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	11 Nov 2020 23:17:14
User entered empty.	System	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192940

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
Temperature

Audit	User	Time (GMT)
User entered '97.2' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192941

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
Chills

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192942

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
Cough

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192943

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
Shortness of Breath

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192944

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
Difficulty Breathing

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192945

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
Fatigue

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192946

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192947

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
Body Aches

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192948

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
Headache

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192949

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
New Loss of Taste

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192950

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
New Loss of Smell

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192951

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
Nasal Congestion

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192952

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192953

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
Nausea

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192954

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
Vomiting

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192955

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
Diarrhea

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192956

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (17)
Generated On: 26 Nov 2020 11:13:54
Sore Throat

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

FDA-CBER-2022-1614-6192957

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 18 (Day 18)'	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192958

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
Date

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192959

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
Assessment Not Done

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192960

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation

Audit	User	Time (GMT)
User entered '99' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192961

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
O2 Saturation Units

Audit	User	Time (GMT)
User entered '%'	System	11 Nov 2020 23:17:55
User entered empty.	System	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192962

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
Temperature

Audit	User	Time (GMT)
User entered '97.2' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192963

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
Chills

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192964

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
Cough

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192965

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
Shortness of Breath

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192966

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
Difficulty Breathing

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192967

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
Fatigue

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192968

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192969

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
Body Aches

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192970

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
Headache

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192971

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
New Loss of Taste

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192972

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
New Loss of Smell

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192973

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
Nasal Congestion

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192974

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192975

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
Nausea

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192976

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
Vomiting

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192977

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
Diarrhea

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192978

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Symptom Log (18)
Generated On: 26 Nov 2020 11:13:54
Sore Throat

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

FDA-CBER-2022-1614-6192979

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:13:54
Date of Visit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:32:40
User entered '8 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:45:32

FDA-CBER-2022-1614-6192980

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:13:54
Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:32:40
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:45:32

FDA-CBER-2022-1614-6192981

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:13:54
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:32:40
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)	14 Sep 2020 15:31:55
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 'YES AND IT IS RECORDED IN ADVERSE EVENTS FORM' (Site from System).	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:50:26
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	10 Sep 2020 22:45:32
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:45:32

FDA-CBER-2022-1614-6192982

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:13:54
Date of Test

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:32:40
User entered '8 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:45:32

FDA-CBER-2022-1614-6192983

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:13:54
Type of Test Performed

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:32:40
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:45:32

FDA-CBER-2022-1614-6192984

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:13:54
Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:32:40
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:45:32

FDA-CBER-2022-1614-6192985

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:13:54
Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:32:40
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:45:32

FDA-CBER-2022-1614-6192986

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:13:54
Lab/ Institution Test Performed

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:32:40
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:45:32

FDA-CBER-2022-1614-6192987

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:13:54
CLIA Certified?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:32:40
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:45:32

FDA-CBER-2022-1614-6192988

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: COVID Diagnostic Test
Generated On: 26 Nov 2020 11:13:54
COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 22:45:32

FDA-CBER-2022-1614-6192989

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6192990

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6192991

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6192992

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Respiratory Rate

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6192993

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Did the subject have Heart Rate ≥ 125 beats per minute

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6192994

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6192995

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6192996

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Heart Rate

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6192997

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
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)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6192998

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6192999

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193000

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Oxygen Saturation

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193001

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193002

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193003

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193004

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
PaO2

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193005

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Did the subject have Respiratory failure?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193006

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193007

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193008

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193009

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
High-Flow Oxygen?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193010

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193011

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193012

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Non-Invasive Ventilation?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193013

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193014

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193015

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Mechanical Ventilation?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193016

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193017

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193018

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
ECMO?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193019

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193020

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193021

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193022

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193023

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193024

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Evidence of Shock Requires Vasopressors

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193025

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193026

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193027

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Acute Renal Dysfunction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193028

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193029

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Hepatic Dysfunction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193030

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193031

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Neurologic Dysfunction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193032

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193033

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Clinical Evidence

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193034

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Date of Assessment

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 21:42:58
User entered '8 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193035

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Radiographical Evidence

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193036

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Date of Assessment

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193037

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Admission to an intensive care unit due to SARS-CoV-2

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193038

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
Start Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193039

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 26 Nov 2020 11:13:54
End Date

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

FDA-CBER-2022-1614-6193040

US3752366
Folder: Covid-19 Assessment 06 Sep 2020
Form: Generate Next COVID-19 Assessment
Generated On: 26 Nov 2020 11:13:54
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:21
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:47:42

FDA-CBER-2022-1614-6193041

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 26 Nov 2020 11:13:54
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

FDA-CBER-2022-1614-6193042

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 26 Nov 2020 11:13:54
Was Saliva Collected?

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 17:59:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 17:59:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 17:59:54
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 22:39:19
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:39:19
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 26 Nov 2020 11:13:54
Date of Collection

Audit	User	Time (GMT)
User entered '10 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 17:59:54
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:39:19
User entered '10 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

FDA-CBER-2022-1614-6193044

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 26 Nov 2020 11:13:54
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

FDA-CBER-2022-1614-6193045

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 26 Nov 2020 11:13:54
Was Saliva Collected?

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 17:59:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 17:59:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 17:59:54
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 22:38:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

FDA-CBER-2022-1614-6193046

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 26 Nov 2020 11:13:54
Date of Collection

Audit	User	Time (GMT)
User entered '12 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 17:59:54
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

FDA-CBER-2022-1614-6193047

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 26 Nov 2020 11:13:54
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

FDA-CBER-2022-1614-6193048

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 26 Nov 2020 11:13:54
Was Saliva Collected?

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 17:59:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 17:59:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 17:59:54
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 22:38:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

FDA-CBER-2022-1614-6193049

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 26 Nov 2020 11:13:54
Date of Collection

Audit	User	Time (GMT)
User entered '14 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 17:59:54
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

FDA-CBER-2022-1614-6193050

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 26 Nov 2020 11:13:54
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

FDA-CBER-2022-1614-6193051

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 26 Nov 2020 11:13:54
Was Saliva Collected?

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 17:59:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 17:59:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 17:59:54
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 22:38:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

FDA-CBER-2022-1614-6193052

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 26 Nov 2020 11:13:54
Date of Collection

Audit	User	Time (GMT)
User entered '16 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 17:59:54
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

FDA-CBER-2022-1614-6193053

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 26 Nov 2020 11:13:54
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

FDA-CBER-2022-1614-6193054

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 26 Nov 2020 11:13:54
Was Saliva Collected?

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 15:21:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 15:21:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:21:50
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 22:38:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 26 Nov 2020 11:13:54
Date of Collection

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21SEP2020 is recorded for Day 14 in EDC, however the same is reported under Day 14 with date 28SEP2020 in PPD Central lab. Please confirm and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 08:03:41
User entered '21 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:21:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

FDA-CBER-2022-1614-6193056

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 26 Nov 2020 11:13:54
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

FDA-CBER-2022-1614-6193057

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 26 Nov 2020 11:13:54
Was Saliva Collected?

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 17:49:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 17:49:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	29 Sep 2020 17:49:49
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 22:38:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 26 Nov 2020 11:13:54
Date of Collection

Audit	User	Time (GMT)
User entered '28 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	29 Sep 2020 17:49:49
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

FDA-CBER-2022-1614-6193059

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 26 Nov 2020 11:13:54
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

FDA-CBER-2022-1614-6193060

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 26 Nov 2020 11:13:54
Was Saliva Collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:48:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 08:53:58
Query 'Data is required. Please complete.' answered with 'Day 28 has not occurred yet' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 21:32:57
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 22:38:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 26 Nov 2020 11:13:54
Date of Collection

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07OCT2020 is recorded as Illness Visit Day 28 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 08:06:29
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07OCT2020 is recorded as Illness Visit Day 28 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'SITE DID NOT HAVE VISIT DAY 28 KIT AVAILABLE THEREFORE UNSCHEDULED KIT USED FOR SUPPLIES' (Site from DM).	Amanda Horn (b) (4) (b) (4)	02 Nov 2020 15:50:46
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07OCT2020 is recorded as Illness Visit Day 28 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 04:38:59
User entered '7 Oct 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:48:12
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

FDA-CBER-2022-1614-6193062

US3752366
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Was this visit performed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:55:52
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:15:28

FDA-CBER-2022-1614-6193063

US3752366
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:55:52
User entered '8 Sep 2020'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:15:28

FDA-CBER-2022-1614-6193064

US3752366
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:55:52
User entered 'Clinic (Clinic)'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:15:28

FDA-CBER-2022-1614-6193065

US3752366
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Folder OID

Audit	User	Time (GMT)
User entered 'SICKD1'	System	08 Sep 2020 16:15:28

FDA-CBER-2022-1614-6193066

US3752366
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Were vital signs assessed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:57:18
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:13:25

FDA-CBER-2022-1614-6193067

US3752366
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:57:19
User entered '8 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:13:25

FDA-CBER-2022-1614-6193068

US3752366
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:57:20
User entered '10:20'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:13:25

FDA-CBER-2022-1614-6193069

US3752366
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '8 Sep 2020 10:20'	System	10 Sep 2020 21:13:25

FDA-CBER-2022-1614-6193070

US3752366
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User closed query 'Please remove leading zero from all values. ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:41:00
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:40:38
Query 'Please remove leading zero from all values. ' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 18:39:49
User entered '98.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 18:39:33
User opened query 'Please remove leading zero from all values. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 15:57:09
User entered '098.0' F	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:13:25

FDA-CBER-2022-1614-6193071

US3752366
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Route of measurement

Audit	User	Time (GMT)
User closed query 'Please provide updated source where route of measurement is noted. ' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 16:07:02
Query 'Please provide updated source where route of measurement is noted. ' answered with 'UPLOADED PER REQUEST' (Site from CRA).	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 14:35:20
User opened query 'Please provide updated source where route of measurement is noted. ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:41:21
User closed query 'Please ensure route of measurement is documented in source. ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:41:21
Query 'Please ensure route of measurement is documented in source. ' answered with 'noted' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 18:40:01
User opened query 'Please ensure route of measurement is documented in source. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 15:57:47
User entered 'Oral (Oral)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:13:25

FDA-CBER-2022-1614-6193072

US3752366
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
If Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:40:57
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:13:25

FDA-CBER-2022-1614-6193073

US3752366
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Pulse *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:40:44
User entered '84' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 18:39:33
User entered '084'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:13:25

FDA-CBER-2022-1614-6193074

US3752366
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Sep 2020 21:13:25

FDA-CBER-2022-1614-6193075

US3752366
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:40:47
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 18:39:33
User entered '016'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:13:25

FDA-CBER-2022-1614-6193076

US3752366
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Sep 2020 21:13:25

FDA-CBER-2022-1614-6193077

US3752366
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:40:53
User entered '144'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:13:25

FDA-CBER-2022-1614-6193078

US3752366
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 21:13:25

FDA-CBER-2022-1614-6193079

US3752366
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:40:55
User entered '100'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:13:25

FDA-CBER-2022-1614-6193080

US3752366
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 21:13:25

FDA-CBER-2022-1614-6193081

US3752366
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:13:54
Was the physical examination performed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:59:08
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:14:11

FDA-CBER-2022-1614-6193082

US3752366
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:13:54
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:59:08
User entered '8 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:14:11

FDA-CBER-2022-1614-6193083

US3752366
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 26 Nov 2020 11:13:54
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:59:17
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:15:03

FDA-CBER-2022-1614-6193084

US3752366
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 26 Nov 2020 11:13:54
Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:59:17
User entered '8 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:15:03

FDA-CBER-2022-1614-6193085

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Was this visit performed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:00:23
User entered 'Yes (Y)'	Patricia Hale (b) (4) (b) (4)	07 Oct 2020 19:05:28

FDA-CBER-2022-1614-6193086

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Recon: Saliva: Sample dated 07OCT2020 for COVID PCR Saliva is reported in PPD central lab, however sample details are missing in EDC. Please complete, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 08:05:48
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 07OCT2020 for COVID PCR Saliva is reported in PPD central lab, however sample details are missing in EDC. Please complete, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 08:05:11
Query 'Per GCL Lab Recon: Saliva: Samples dated 22OCT2020 for Day 9, 28OCT2020 for Day 3 is reported under Illness visit in PPD central lab, however saliva details are missing in EDC. Please complete, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:56:52
User opened query 'Per GCL Lab Recon: Saliva: Samples dated 22OCT2020 for Day 9, 28OCT2020 for Day 3 is reported under Illness visit in PPD central lab, however saliva details are missing in EDC. Please complete, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:56:37
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:00:23
User entered '07 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 19:05:28

FDA-CBER-2022-1614-6193087

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:00:23
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	07 Oct 2020 19:05:28

FDA-CBER-2022-1614-6193088

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 26 Nov 2020 11:13:54
Folder OID

Audit	User	Time (GMT)
User entered 'SICKD28'	System	07 Oct 2020 19:05:28

FDA-CBER-2022-1614-6193089

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Were vital signs assessed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:02:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 19:06:38

FDA-CBER-2022-1614-6193090

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:02:18
User entered '07 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 19:06:38

FDA-CBER-2022-1614-6193091

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:02:20
User entered '13:20'	(b) (4), (b) (6)	07 Oct 2020 19:06:38

FDA-CBER-2022-1614-6193092

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '07 Oct 2020 13:20'	System	07 Oct 2020 19:06:38

FDA-CBER-2022-1614-6193093

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Temperature *(xxx.x)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:03:58
User entered '98.2' F	(b) (4), (b) (6)	07 Oct 2020 19:06:38

FDA-CBER-2022-1614-6193094

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Route of measurement

Audit	User	Time (GMT)
User closed query 'Please ensure route of measurement is documented in source. ' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 16:06:41
Query 'Please ensure route of measurement is documented in source. ' answered with 'confirmed' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 13:27:40
User opened query 'Please ensure route of measurement is documented in source. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 16:04:15
User entered 'Oral (Oral)'	(b) (4), (b) (6)	07 Oct 2020 19:06:38

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
If Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:04:23
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:06:38

FDA-CBER-2022-1614-6193096

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Pulse *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:04:26
User entered '76'	(b) (4), (b) (6)	07 Oct 2020 19:06:38

FDA-CBER-2022-1614-6193097

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Oct 2020 19:06:38

FDA-CBER-2022-1614-6193098

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:04:28
User entered '16'	(b) (4), (b) (6)	07 Oct 2020 19:06:38

FDA-CBER-2022-1614-6193099

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Oct 2020 19:06:38

FDA-CBER-2022-1614-6193100

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:04:30
User entered '114'	(b) (4), (b) (6)	07 Oct 2020 19:06:38

FDA-CBER-2022-1614-6193101

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Oct 2020 19:06:38

FDA-CBER-2022-1614-6193102

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:04:32
User entered '76'	(b) (4), (b) (6)	07 Oct 2020 19:06:38

FDA-CBER-2022-1614-6193103

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 11:13:54
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Oct 2020 19:06:38

FDA-CBER-2022-1614-6193104

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:13:54
Was the physical examination performed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:04:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 19:06:57

FDA-CBER-2022-1614-6193105

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 11:13:54
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:04:46
User entered '07 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 19:06:57

FDA-CBER-2022-1614-6193106

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:13:54

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation:Saliva: Sample dated 07OCT2020 is recorded under this visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:32:13
Query 'Per GCL Lab Reconciliation:Saliva: Sample dated 07OCT2020 is recorded under this visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'PER EPIP RESPONSE, VISIT 2 AND DAY 28 CONVALESCENT WERE COMBINED. SITE DID NOT HAVE DAY 28 KIT STOCKED THEREFORE UNSCHEDULED KIT WAS USED TO COLLECT SAMPLE. ' (Site from DM).	Amanda Horn (b) (4) (b) (4)	28 Oct 2020 15:13:20
User opened query 'Per GCL Lab Reconciliation:Saliva: Sample dated 07OCT2020 is recorded under this visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:28:27
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:04:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:11:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:09:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 19:08:48

US3752366
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 26 Nov 2020 11:13:54
Date of Collection

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 07 OCT 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 05:23:07
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:04:54
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:11:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:09:40
User entered '07 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 19:08:48

FDA-CBER-2022-1614-6193108

US3752366
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 26 Nov 2020 11:13:54
Did the participant experience any adverse events?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:16:11
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:08:41

FDA-CBER-2022-1614-6193109

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
AEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:01
User entered 'USA-US113-2020-mRNA-1273-P301000001'	System	12 Sep 2020 16:14:42
User entered 'New'	(b) (4), (b) (6)	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193110

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Adverse event

Audit	User	Time (GMT)
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)	23 Nov 2020 20:10:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:10:22
Data point term sent to Coder	System	23 Nov 2020 20:08:56
User closed query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	System	23 Nov 2020 20:08:29
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' answered with 'updated' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 20:08:29
Coding entries removed.	(b) (4), (b) (6)	23 Nov 2020 20:08:21
User entered 'COVID-19' reason for change: Per Query Resolution	(b) (4), (b) (6)	23 Nov 2020 20:08:21
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 12:23:57
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)	11 Nov 2020 23:28:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 23:28:38
Data point term sent to Coder	System	11 Nov 2020 23:27:57
DataPoint Un-verified.	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:27:23
Coding entries removed.	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:27:23
User entered 'SYMPTOMATIC COVID-19' reason for change: Per Query Resolution	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:27:23

FDA-CBER-2022-1614-6193111

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Adverse event

Audit	User	Time (GMT)
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection' canceled (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 14:49:10
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 14:48:55
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User closed query 'PV Query: Please update event term to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 13:56:56
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)	15 Sep 2020 13:26:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 13:26:43
Query 'PV Query: Please update event term to COVID-19.' answered with 'updated' (Site from Safety).	Haylee Rowe (b) (4) (b) (4)	15 Sep 2020 13:25:24
Data point term sent to Coder	System	15 Sep 2020 13:25:22
Coding entries removed.	Haylee Rowe (b) (4) (b) (4)	15 Sep 2020 13:25:09
User entered 'COVID-19' reason for change: Per Query Resolution	Haylee Rowe (b) (4) (b) (4)	15 Sep 2020 13:25:09
User opened query 'PV Query: Please update event term to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:53:47
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)	11 Sep 2020 05:07:48
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:07:48
Data point term sent to Coder	System	10 Sep 2020 22:31:59
User entered 'CONFIRMED SYMPTOMATIC COVID-19 CASE'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193112

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193113

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193114

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User closed query 'PV Query: Please clarify event onset date. The date is listed as 04 Sep 2020 however, there are no symptoms or COVID test for that date. Please update as applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 17:24:35
Query 'PV Query: Please clarify event onset date. The date is listed as 04 Sep 2020 however, there are no symptoms or COVID test for that date. Please update as applicable.' answered with 'data is correct' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 19:07:51
User opened query 'PV Query: Please clarify event onset date. The date is listed as 04 Sep 2020 however, there are no symptoms or COVID test for that date. Please update as applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 13:06:45
User closed query 'PV Query: Please clarify event onset date. The date is listed as 04 Sep 2020 however, there are no symptoms or COVID test for that date. Please update as applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:10:48
Query 'PV Query: Please clarify event onset date. The date is listed as 04 Sep 2020 however, there are no symptoms or COVID test for that date. Please update as applicable.' answered with 'COUGH, CHILLS, AND RHINORRHEA LISTED WITH START DATE 04SEP2020' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:17:19
User opened query 'PV Query: Please clarify event onset date. The date is listed as 04 Sep 2020 however, there are no symptoms or COVID test for that date. Please update as applicable.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:54:23
User entered '4 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:15:29
User entered '10 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193116

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
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	10 Sep 2020 22:32:26
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:32:26
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	10 Sep 2020 22:31:14
User entered '15:58'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193117

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 22:32:26
User entered '10 Sep 2020 15:58'	System	10 Sep 2020 22:31:14

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	21 Sep 2020 15:15:26
User entered 'No (N)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:15:26
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	21 Sep 2020 15:14:57
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User closed query 'PV Query: Please provide the event end date (date of resolution of symptoms).' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:10:53
Query 'PV Query: Please provide the event end date (date of resolution of symptoms).' answered with '16SEP2020 IS THE FIRST DAY WITHOUT SYMPTOMS' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:15:59
User entered '16 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:14:57
User opened query 'PV Query: Please provide the event end date (date of resolution of symptoms).' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:51:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193120

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193121

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193122

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered 'Grade 1/Mild (Grade 1/Mild)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193125

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193126

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	10 Sep 2020 22:32:26
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	10 Sep 2020 22:32:26
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	10 Sep 2020 22:31:14
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193127

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193128

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193129

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:32:26
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193130

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193131

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193132

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193133

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193134

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User closed query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:34:32
Query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' answered with 'SUBJECT IS A PHYSICIAN WHO HAD KNOWN EXPOSURE TO A COVID POSITIVE PATIENT ON 31AUG WHICH WAS 2 DAYS PRIOR TO V1 AND 5 DAYS PRIOR TO ONSET OF SYMPTOMS.' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:50:43
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:50:36
User opened query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 15:15:52
User closed query 'PV Query: Please provide rationale for assessing the AE of COVID-19 as related to blinded study medication.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 17:24:42
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	29 Sep 2020 20:18:18
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	29 Sep 2020 19:41:20
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	29 Sep 2020 19:41:20
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 19:41:20
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	29 Sep 2020 19:25:53

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Relationship to investigational product

Audit	User	Time (GMT)
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	29 Sep 2020 19:24:57
Query 'PV Query: Please provide rationale for assessing the AE of COVID-19 as related to blinded study medication.' answered with 'subject was exposed to someone with COVID on the monday prior to his first injection' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 19:23:32
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	29 Sep 2020 19:22:35
User entered 'Not Related (NOT RELATED)' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 19:22:35
User opened query 'PV Query: Please provide rationale for assessing the AE of COVID-19 as related to blinded study medication.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 13:09:48
User closed query 'PV Query: Please provide the investigator's causality assessment between the event and the study drug. As the subject received study drug, appropriate response would be related or not related.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:11:03
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	21 Sep 2020 15:20:51
User entered 'Related (RELATED)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:20:51
Query 'PV Query: Please provide the investigator's causality assessment between the event and the study drug. As the subject received study drug, appropriate response would be related or not related.' answered with 'SUBJECT HAD KNOWN EXPOSURE TO A PATIENT WITH POSITIVE COVID 19 RESULTS 5 DAYS PRIOR TO DEVELOPING SYMPTOMS' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:19:56
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	21 Sep 2020 15:19:09

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Relationship to investigational product

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:19:09
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	21 Sep 2020 15:18:05
User entered 'Related (RELATED)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:18:05
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	21 Sep 2020 15:14:57
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:14:57
User opened query 'PV Query: Please provide the investigator's causality assessment between the event and the study drug. As the subject received study drug, appropriate response would be related or not related.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:53:24
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	10 Sep 2020 22:37:52
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	10 Sep 2020 22:32:26
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	10 Sep 2020 22:32:26
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:32:26
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	10 Sep 2020 22:31:14
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193137

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Relationship to Study Procedure

Audit	User	Time (GMT)
User closed query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 10:55:00
Query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses' answered with 'Subject did not receive additional doses.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 14:15:14
User opened query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 14:49:40
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User closed query 'Per CDM: please review and reconcile Relationship to Study Procedure, since event started after first dose. Per CRF Completion Guidelines, Not Applicable is expected if clinical event is prior to first dose/investigational product.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 08:37:14
Query 'Per CDM: please review and reconcile Relationship to Study Procedure, since event started after first dose. Per CRF Completion Guidelines, Not Applicable is expected if clinical event is prior to first dose/investigational product.' answered with 'SUBJECT HAD KNOWN EXPOSURE TO A PATIENT WITH POSITIVE COVID 19 RESULTS 5 DAYS PRIOR TO DEVELOPING SYMPTOMS' (Site from DM).	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:19:58
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:19:09
User entered 'Related (RELATED)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:18:05
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:14:57

FDA-CBER-2022-1614-6193138

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Relationship to Study Procedure

Audit	User	Time (GMT)
User opened query 'Per CDM: please review and reconcile Relationship to Study Procedure, since event started after first dose. Per CRF Completion Guidelines, Not Applicable is expected if clinical event is prior to first dose/investigational product.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 16:08:44
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:32:26
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193139

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 20:10:02
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding End of Study/Discontinuation record that match this information. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:10:00
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'REASON FOR DOSING D/C IS DUE TO SUBJECT CONTRACTING COVID, THERE IS AN OPTION FOR THAT ON THE D/C MENU' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 14:15:13
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding End of Study/Discontinuation record that match this information. Please review and update applicable details as appropriate. Otherwise, clarify.' answered with 'SUBJECT WAS WITHDRAW FROM IP BUT IS CONTINUING IN THE STUDY WITH FUTURE VISITS' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:10:12
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	26 Oct 2020 17:02:42
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding End of Study/Discontinuation record that match this information. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 00:35:32

FDA-CBER-2022-1614-6193140

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User closed query 'PV Query: Per protocol, if a subject has a positive COVID-19 result prior to second vaccination dosing, study drug should be "withdrawn" and second dosing not given. This is not the same as withdrawing from study, only withdrawing from study drug dosing. Please update action taken accordingly.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:34:45
User closed query 'Per MM, please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:18:31
Query 'PV Query: Per protocol, if a subject has a positive COVID-19 result prior to second vaccination dosing, study drug should be "withdrawn" and second dosing not given. This is not the same as withdrawing from study, only withdrawing from study drug dosing. Please update action taken accordingly.' answered with 'SUBJECT RETURNED FOR V2 BUT IP NOT GIVEN. SUBJECT WILL CONTINUE OTHER STUDY VISITS' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:52:17
Query 'Per MM, please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose. ' answered with 'SUBJECT RETURNED FOR V2 BUT IP NOT GIVEN. SUBJECT WILL CONTINUE OTHER STUDY VISITS' (Site from DM).	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:52:14
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:51:59

FDA-CBER-2022-1614-6193141

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'PV Query: Per protocol, if a subject has a positive COVID-19 result prior to second vaccination dosing, study drug should be "withdrawn" and second dosing not given. This is not the same as withdrawing from study, only withdrawing from study drug dosing. Please update action taken accordingly.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 15:16:24
User opened query 'Per MM, please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 18:59:41
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 20:18:18
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 19:25:53
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 19:24:57
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. If patient will be receiving further IP doses, please update action taken to no change.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:11:16
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. If patient will be receiving further IP doses, please update action taken to no change.' answered with 'SUBJECT WITH POSITIVE COVID RESULTS WILL NOT BE ELIGIBLE FOR DOSE 2 OF IP. ' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:20:00
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:14:57

FDA-CBER-2022-1614-6193142

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. If patient will be receiving further IP doses, please update action taken to no change.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:53:09
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:37:52
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #2 recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 23:32:09
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #2 recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 22:45:10
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 22:45:02
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #2 recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 05:52:53
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 17:09:43
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 17:09:43
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193144

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Concomitant Medication

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 22:45:02
User closed query 'Per DM CLR - RQ: Site's response noted. However, this AE is not the CM indication. Please review and reconcile AE term and CM indication, so there will be an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 12:39:50
Query 'Per DM CLR - RQ: Site's response noted. However, this AE is not the CM indication. Please review and reconcile AE term and CM indication, so there will be an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 17:09:49
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 17:09:43
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 17:09:43
User opened query 'Per DM CLR - RQ: Site's response noted. However, this AE is not the CM indication. Please review and reconcile AE term and CM indication, so there will be an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:23:29
Query 'Per DM CLR - RQ: Site's response noted. However, this is not the CM indication. Please review and reconcile AE term and CM indication, so there will be an appropriate match. Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:23:17
User opened query 'Per DM CLR - RQ: Site's response noted. However, this is not the CM indication. Please review and reconcile AE term and CM indication, so there will be an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:23:03
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed record that is indicated for this AE. Please reconcile and update the Indication of the corresponding ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 10:53:48

FDA-CBER-2022-1614-6193145

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Concomitant Medication

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed record that is indicated for this AE. Please reconcile and update the Indication of the corresponding ConMed treatment for this AE as appropriate. Otherwise, clarify.' answered with 'Subject began Tylenol 05SEP2020.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 14:17:09
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed record that is indicated for this AE. Please reconcile and update the Indication of the corresponding ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:40:23
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered '1'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193146

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193147

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User closed query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:11:20
Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with '16SEP2020 SUBJECT REPORTS RESOLUTION OF ALL SYMPTOMS' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:20:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:14:57
User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:52:55
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193148

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193149

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered 'SUBJECT EXPOSED TO COVID POSITIVE PERSON THE MONDAY PRIOR TO FIRST DOSE. INVESTIGATIONAL PRODUCT WITHDRAWN' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:52:49
User closed query 'PV Query: Please fill out the COVID-19 assessment pages from 04-08 Sep 2020, as the subject began having COVID-19 symptoms on 04 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 17:24:47
Query 'PV Query: Please fill out the COVID-19 assessment pages from 04-08 Sep 2020, as the subject began having COVID-19 symptoms on 04 Sep 2020.' answered with 'began having symptoms on the 4th but wasn't seen in the clinic until the 8th therefore he didn't have telehealth visits at that time. ' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 21:31:45
User entered 'Subject exposed to COVID positive person the monday prior to first dose. 2nd dose of IP held' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 20:21:09
User opened query 'PV Query: Please fill out the COVID-19 assessment pages from 04-08 Sep 2020, as the subject began having COVID-19 symptoms on 04 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 13:09:33
User closed query 'PV Query: Did the subject have any known exposure to COVID-19 or risk factors?' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:12:00
User closed query 'PV Query: Please confirm if the subject was experiencing fever/chills on 05 Sep (per the indication for Tylenol starting on 05 Sep).' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:11:55
User closed query 'PV Query: Is this a baseline positive case or was an additional test performed on 08 Sep 2020? If test was collected around 08 Sep, please provide date test was performed along with date it resulted.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:11:51
User closed query 'PV Query: Please provide the results of the swab collected on 02 Sep 2020, along with the date it resulted.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:11:39

FDA-CBER-2022-1614-6193150

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any additional 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).' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:11:33
Query 'PV Query: Please provide any additional 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).' answered with 'NO OTHER MEDICAL INTERVENTIONS OR SURGICAL TREATMENTS. THE ONLY CONCOMITANT MEDICATION WAS THE TYLENOL LISTED. ' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:14:53
Query 'PV Query: Did the subject have any known exposure to COVID-19 or risk factors?' answered with 'HE HAD KNOWN EXPOSURE ON 31 AUG. HE IS A FAMILY PHYSICIAN AND SAW THE PATIENT ON 31 AUG AND WAS NO AWARE OF THE POSITIVE RESULTS AT THE TIME OF HIS 1ST VISIT ON 02 SEP IN WHICH HE RECEIVED THE FIRST INJECTION.' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:13:48
Query 'PV Query: Please confirm if the subject was experiencing fever/chills on 05 Sep (per the indication for Tylenol starting on 05 Sep).' answered with 'FEVER/CHILLS BEGAN 05 SEP' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:12:18
Query 'PV Query: Is this a baseline positive case or was an additional test performed on 08 Sep 2020? If test was collected around 08 Sep, please provide date test was performed along with date it resulted.' answered with 'ADDITIONAL TEST PERFORMED 08 SEP AT ILLNESS VISIT' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:11:11
Query 'PV Query: Please provide the results of the swab collected on 02 Sep 2020, along with the date it resulted.' answered with 'NEGATIVE BASELINE PCR RESULTS ON 02SEP2020' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:10:45

FDA-CBER-2022-1614-6193151

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Did the subject have any known exposure to COVID-19 or risk factors?' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:54:42
User opened query 'PV Query: Please confirm if the subject was experiencing fever/chills on 05 Sep (per the indication for Tylenol starting on 05 Sep).' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:54:35
User opened query 'PV Query: Is this a baseline positive case or was an additional test performed on 08 Sep 2020? If test was collected around 08 Sep, please provide date test was performed along with date it resulted.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:54:06
User opened query 'PV Query: Please provide the results of the swab collected on 02 Sep 2020, along with the date it resulted.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:53:57
User opened query 'PV Query: Please provide any additional 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).' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:53:37
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193152

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	10 Sep 2020 22:31:14

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193154

US3752366
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 11:13:54
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	10 Sep 2020 22:31:14

FDA-CBER-2022-1614-6193155

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 26 Nov 2020 11:13:54
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Per Diary Dose 1 Day 4-5, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 15:26:55
Query 'Per DM CLR: Per Diary Dose 1 Day 4-5, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'UPDATED' (Site from DM).	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:23:28
User opened query 'Per DM CLR: Per Diary Dose 1 Day 4-5, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 16:15:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 21:08:50

FDA-CBER-2022-1614-6193156

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:13:54
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 21:11:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 21:11:52
Data point term sent to Coder	System	03 Sep 2020 21:10:38
User entered 'Multivitamin'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

FDA-CBER-2022-1614-6193157

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:13:54
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:21:21
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

FDA-CBER-2022-1614-6193158

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:13:54
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'Supplement'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

FDA-CBER-2022-1614-6193159

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:13:54
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered '1'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

FDA-CBER-2022-1614-6193160

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:13:54
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

FDA-CBER-2022-1614-6193161

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:13:54
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:09:38

FDA-CBER-2022-1614-6193162

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:13:54
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

FDA-CBER-2022-1614-6193163

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:13:54
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered '2 to 3 times per week'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

FDA-CBER-2022-1614-6193164

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:13:54
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

FDA-CBER-2022-1614-6193165

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:13:54
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:09:38

FDA-CBER-2022-1614-6193166

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:13:54
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'un UNK 2019'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

FDA-CBER-2022-1614-6193167

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:13:54
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

FDA-CBER-2022-1614-6193168

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:13:54
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

FDA-CBER-2022-1614-6193169

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:13:54
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:09:38

FDA-CBER-2022-1614-6193170

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:13:54
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

FDA-CBER-2022-1614-6193171

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:13:54
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:09:38

FDA-CBER-2022-1614-6193172

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:13:54
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:09:38

FDA-CBER-2022-1614-6193173

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 11:13:54
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:09:38

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 23:28:37
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 Nov 2020 23:28:37
Data point term sent to Coder	System	11 Nov 2020 23:27:56
Coding entries removed.	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:27:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:01:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:01:52
Data point term sent to Coder	System	08 Sep 2020 16:00:56
User entered 'TYLENOL'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

FDA-CBER-2022-1614-6193175

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

FDA-CBER-2022-1614-6193176

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54
Indication

Audit	User	Time (GMT)
DataPoint Un-verified.	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:27:40
User entered 'SYMPTOMATIC COVID-19' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:27:40
User closed query 'Per CDM: Thank you for your response. Please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria CD: please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 15:22:11
Query 'Per CDM: Thank you for your response. Please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria CD: please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria.' answered with 'FEVER, CHILLS OCCURRED DAY 5 FOLLOWING INJECTION, DOES NOT MEET REPORTING CRITERIA' (Site from DM).	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:20:51
User opened query 'Per CDM: Thank you for your response. Please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria CD: please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 21:09:28
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER, CHILLS is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 21:08:33

FDA-CBER-2022-1614-6193177

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54
Indication

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER, CHILLS is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria.' answered with 'Subjected noted chills in eDiary.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 17:20:26
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER, CHILLS is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:51:49
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'FEVER, CHILLS'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

FDA-CBER-2022-1614-6193178

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered '1000'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

FDA-CBER-2022-1614-6193179

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

FDA-CBER-2022-1614-6193180

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

FDA-CBER-2022-1614-6193181

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54
Frequency

Audit	User	Time (GMT)
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	08 Nov 2020 19:20:47
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	08 Nov 2020 19:20:47
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	08 Nov 2020 19:20:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'once (ONCE)'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

FDA-CBER-2022-1614-6193183

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

FDA-CBER-2022-1614-6193184

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

FDA-CBER-2022-1614-6193185

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Un-verified.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:20:38
User entered '6 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:20:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered '5 Sep 2020'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

FDA-CBER-2022-1614-6193186

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered '0'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

FDA-CBER-2022-1614-6193187

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

FDA-CBER-2022-1614-6193188

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	08 Nov 2020 19:20:47
DataPoint Un-verified.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:20:47
User entered '6 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:20:47
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	08 Nov 2020 19:20:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered '5 Sep 2020'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 12:34:11
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' answered with 'changed to no' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:12:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 16:12:04
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 05:52:27
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 21:09:57
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'changed' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 17:18:39
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 17:18:27
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:18:27
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:43:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52

FDA-CBER-2022-1614-6193190

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

FDA-CBER-2022-1614-6193191

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 16:00:41

FDA-CBER-2022-1614-6193192

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 16:00:41

FDA-CBER-2022-1614-6193193

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 11:13:54
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 16:00:41

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:13:54
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 23:29:38
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 Nov 2020 23:29:38
Data point term sent to Coder	System	11 Nov 2020 23:28:58
Coding entries removed.	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:28:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 11:46:33
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 11:46:33
Data point term sent to Coder	System	05 Nov 2020 16:43:30
User entered 'Seasonal influenza vaccine'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

FDA-CBER-2022-1614-6193195

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:13:54
Prophylaxis

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

FDA-CBER-2022-1614-6193196

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:13:54
Indication

Audit	User	Time (GMT)
User entered 'PROPHYLAXIS FOR SEASONAL INFLUENZA' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:28:48
User entered 'Prophylaxix for seasonal influenza'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

FDA-CBER-2022-1614-6193197

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:13:54
Dose per administration

Audit	User	Time (GMT)
User entered '0.5'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

FDA-CBER-2022-1614-6193198

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:13:54
Dose unit

Audit	User	Time (GMT)
User entered 'mL (mL)'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

FDA-CBER-2022-1614-6193199

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:13:54
If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:42:31

FDA-CBER-2022-1614-6193200

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:13:54
Frequency

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

FDA-CBER-2022-1614-6193201

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:13:54
If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:42:31

FDA-CBER-2022-1614-6193202

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:13:54
Route of administration

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

FDA-CBER-2022-1614-6193203

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:13:54
If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:42:31

FDA-CBER-2022-1614-6193204

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:13:54
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '05 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

FDA-CBER-2022-1614-6193205

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:13:54
Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

FDA-CBER-2022-1614-6193206

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:13:54
Ongoing?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

FDA-CBER-2022-1614-6193207

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:13:54
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '05 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

FDA-CBER-2022-1614-6193208

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:13:54
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

FDA-CBER-2022-1614-6193209

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:13:54
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:42:31

FDA-CBER-2022-1614-6193210

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:13:54
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:42:31

FDA-CBER-2022-1614-6193211

US3752366
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 11:13:54
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:42:31

US3752366
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 26 Nov 2020 11:13:54
Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Date of dose discontinuation does not match with any dose dates.Please reconcile, review and update or else clarify' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:17:51
Query 'Per CDM: Date of dose discontinuation does not match with any dose dates.Please reconcile, review and update or else clarify' answered with 'UNSURE WHICH DATE TO USE. HE WAS NOT SEEN FOR V2 AS HE WAS COVID POSITIVE IN THE 28 DAYS FOLLOWING DOSE 1. DATE ENTERED REFLECTS DATE OF ILLNESS VISIT.' (Site from DM).	Amanda Horn (b) (4) (b) (4)	28 Oct 2020 15:17:18
User entered '8 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	28 Oct 2020 15:17:14
User opened query 'Per CDM: Date of dose discontinuation does not match with any dose dates.Please reconcile, review and update or else clarify' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:29:06
User entered '16 Sep 2020'	(b) (4), (b) (6)	26 Oct 2020 17:02:42

FDA-CBER-2022-1614-6193213

US3752366
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 26 Nov 2020 11:13:54
Primary reason for dosing discontinuation

Audit	User	Time (GMT)
User closed query 'Per CDM: Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 10:18:51
Query 'Per CDM: Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates' answered with 'UPDATED' (Site from DM).	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 19:56:37
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 19:56:04
User opened query 'Per CDM: Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:49:45
User closed query 'Per CDM: AE #1 Covid-19 has IP withdrawn due to AE. If this AE was the reason for IP withdrawal then AE should be selected. Please clarify ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:35:12
Query 'Per CDM: AE #1 Covid-19 has IP withdrawn due to AE. If this AE was the reason for IP withdrawal then AE should be selected. Please clarify ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 21:48:50
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:48:38
User opened query 'Per CDM: AE #1 Covid-19 has IP withdrawn due to AE. If this AE was the reason for IP withdrawal then AE should be selected. Please clarify ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:25:15
User closed query 'Per CDM: AE #1 records Action taken with investigational product as Investigational Product Withdrawn However, AE is not slecect as primary reason. Please reconcile' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:25:15
Query 'Per CDM: AE #1 records Action taken with investigational product as Investigational Product Withdrawn However, AE is not slecect as primary reason. Please reconcile' answered with 'SARS-COV-2 POSITIVE WITHIN 28 DAYS OF DOSE 1. WHICH WOULD BE APPROPRIATE TO CHOOSE? AE OR SARS-COV-2?' (Site from DM).	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:25:42
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 18:14:34
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 18:12:24

FDA-CBER-2022-1614-6193214

US3752366
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 26 Nov 2020 11:13:54
Primary reason for dosing discontinuation

Audit	User	Time (GMT)
User opened query 'Per CDM: AE #1 records Action taken with investigational product as Investigational Product Withdrawn However, AE is not slecect as primary reason. Please reconcile' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 17:38:30
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4), (b) (6)	26 Oct 2020 17:02:42

FDA-CBER-2022-1614-6193215

US3752366
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 26 Nov 2020 11:13:54
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	19 Nov 2020 19:56:20
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 19:56:20
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	19 Nov 2020 19:56:04
User entered 'COVID-19 contact' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:50:31
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	09 Nov 2020 21:50:21
User entered 'COVID-19' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:50:21
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	09 Nov 2020 21:48:38
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	06 Nov 2020 18:14:34
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	06 Nov 2020 18:12:24
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 17:02:42

FDA-CBER-2022-1614-6193216

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'USA-US113-2020-MRNA-1273-P301000001'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193217

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193218

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193219

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193220

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193221

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193222

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193223

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193224

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Priyantha'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193225

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Wijewardane'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '9601 Baptist Health Dr Medical towers 1 Suite 310'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193227

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'Little Rock'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193228

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'AR'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193229

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '72209'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193230

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:57:18
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'US' (non-conformant).	System	12 Sep 2020 16:16:21

FDA-CBER-2022-1614-6193231

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	08 Oct 2020 13:35:22
User entered '4'	System	30 Sep 2020 17:25:10
User entered '3'	System	22 Sep 2020 15:12:27
User entered '2'	System	16 Sep 2020 13:57:30
User entered '1'	System	12 Sep 2020 16:16:21

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'USA-US113-2020-MRNA-1273-P301000001'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193233

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193234

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193235

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193236

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193237

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193238

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193239

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193240

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Priyantha'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193241

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Wijewardane'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193242

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '9601 Baptist Health Dr Medical towers 1 Suite 310'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193243

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'Little Rock'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193244

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'AR'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193245

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '72209'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193246

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:57:18
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'US' (non-conformant).	System	12 Sep 2020 16:16:21

FDA-CBER-2022-1614-6193247

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	08 Oct 2020 13:35:22
User entered '4'	System	30 Sep 2020 17:25:10
User entered '3'	System	22 Sep 2020 15:12:27
User entered '2'	System	16 Sep 2020 13:57:30
User entered '1'	System	12 Sep 2020 16:16:21

FDA-CBER-2022-1614-6193248

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form (1)
Generated On: 26 Nov 2020 11:13:54
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
User entered '12/Sep/2020 12:16'	System	12 Sep 2020 16:16:21

FDA-CBER-2022-1614-6193249

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form (1)
Generated On: 26 Nov 2020 11:13:54
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)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered '1'	(b) (4), (b) (6)	12 Sep 2020 16:16:21

FDA-CBER-2022-1614-6193250

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'USA-US113-2020-MRNA-1273-P301000001'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193251

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193252

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193253

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193254

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193255

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193256

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193257

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193258

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Priyantha'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193259

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Wijewardane'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193260

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '9601 Baptist Health Dr Medical towers 1 Suite 310'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193261

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'Little Rock'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193262

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'AR'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193263

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '72209'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193264

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:57:18
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'US' (non-conformant).	System	12 Sep 2020 16:16:21

FDA-CBER-2022-1614-6193265

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	08 Oct 2020 13:35:22
User entered '4'	System	30 Sep 2020 17:25:10
User entered '3'	System	22 Sep 2020 15:12:27
User entered '2'	System	16 Sep 2020 13:57:30
User entered '1'	System	12 Sep 2020 16:16:21

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form (2)
Generated On: 26 Nov 2020 11:13:54
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
User entered '16/Sep/2020 09:57'	System	16 Sep 2020 13:57:30

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form (2)
Generated On: 26 Nov 2020 11:13:54
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)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 15:12:14
User entered '1'	(b) (4), (b) (6)	16 Sep 2020 13:57:30

FDA-CBER-2022-1614-6193268

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'USA-US113-2020-MRNA-1273-P301000001'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193269

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193270

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193271

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193272

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193273

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193274

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193275

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193276

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Priyantha'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193277

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Wijewardane'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193278

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '9601 Baptist Health Dr Medical towers 1 Suite 310'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193279

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'Little Rock'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193280

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'AR'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193281

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '72209'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193282

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:57:18
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'US' (non-conformant).	System	12 Sep 2020 16:16:21

FDA-CBER-2022-1614-6193283

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	08 Oct 2020 13:35:22
User entered '4'	System	30 Sep 2020 17:25:10
User entered '3'	System	22 Sep 2020 15:12:27
User entered '2'	System	16 Sep 2020 13:57:30
User entered '1'	System	12 Sep 2020 16:16:21

FDA-CBER-2022-1614-6193284

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form (3)
Generated On: 26 Nov 2020 11:13:54
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
User entered '22/Sep/2020 11:12'	System	22 Sep 2020 15:12:27

FDA-CBER-2022-1614-6193285

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form (3)
Generated On: 26 Nov 2020 11:13:54
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)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:24:57
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 15:12:27

FDA-CBER-2022-1614-6193286

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'USA-US113-2020-MRNA-1273-P301000001'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193287

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193288

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193289

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193290

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193291

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193292

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193293

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193294

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Priyantha'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193295

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Wijewardane'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193296

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '9601 Baptist Health Dr Medical towers 1 Suite 310'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193297

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'Little Rock'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193298

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'AR'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193299

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '72209'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193300

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:57:18
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'US' (non-conformant).	System	12 Sep 2020 16:16:21

FDA-CBER-2022-1614-6193301

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	08 Oct 2020 13:35:22
User entered '4'	System	30 Sep 2020 17:25:10
User entered '3'	System	22 Sep 2020 15:12:27
User entered '2'	System	16 Sep 2020 13:57:30
User entered '1'	System	12 Sep 2020 16:16:21

FDA-CBER-2022-1614-6193302

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form (4)
Generated On: 26 Nov 2020 11:13:54
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
User entered '30/Sep/2020 17:25'	System	30 Sep 2020 17:25:10

FDA-CBER-2022-1614-6193303

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form (4)
Generated On: 26 Nov 2020 11:13:54
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)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:35:02
User entered '1'	(b) (4), (b) (6)	30 Sep 2020 17:25:10

FDA-CBER-2022-1614-6193304

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'USA-US113-2020-MRNA-1273-P301000001'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193305

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193306

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193307

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193308

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193309

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193310

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193311

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

FDA-CBER-2022-1614-6193312

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Priyantha'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193313

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Wijewardane'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193314

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '9601 Baptist Health Dr Medical towers 1 Suite 310'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193315

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'Little Rock'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193316

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'AR'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193317

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '72209'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

FDA-CBER-2022-1614-6193318

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:57:18
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'US' (non-conformant).	System	12 Sep 2020 16:16:21

FDA-CBER-2022-1614-6193319

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 11:13:54
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	08 Oct 2020 13:35:22
User entered '4'	System	30 Sep 2020 17:25:10
User entered '3'	System	22 Sep 2020 15:12:27
User entered '2'	System	16 Sep 2020 13:57:30
User entered '1'	System	12 Sep 2020 16:16:21

FDA-CBER-2022-1614-6193320

US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form (5)
Generated On: 26 Nov 2020 11:13:54
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
User entered '08/Oct/2020 13:35'	System	08 Oct 2020 13:35:22

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US3752366
Folder: SAE USA-US113-2020-MRNA-1273-P301000001
Form: Safety Report Form (5)
Generated On: 26 Nov 2020 11:13:54
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)	15 Oct 2020 03:28:34
User entered '1'	(b) (4), (b) (6)	08 Oct 2020 13:35:22

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