US3432334 (Prod: Brigham and Womens Hospital)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:24:33

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US3432334
Form: Participant Creation
Generated On: 26 Nov 2020 09:24:33

Participant ID	US3432334

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-5939363

US3432334
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 09:24:33

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

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US3432334
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:24:33

Date of Birth (MMM yyyy)	(b) (6) 1991
Age	29
Age Units	YEARS
Age (Derived)	29
Sex	Female ☐ Male ■
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ■ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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US3432334
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:24:33

Date of Informed Consent *(dd MMM yyyy)*	28 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐ Amendment 2 ☐ Amendment 3 ■ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ■ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ■
If Yes, previous participant number	
Enrollment Trigger	1

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

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Were any significant conditions reported?	Yes ■ No ☐

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US3432334
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:24:33

Condition	MILD ASTHMA
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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US3432334
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	28 AUG 2020
Time of assessment *(00:00-23:59)*	09:37 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 09:37
Height *(xxx.x)*	170.5 cm
Weight *(xxx.x)*	72.5 kg
BMI *(xxx.x)*	24.93959 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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US3432334
Folder: Screening
Form: Physical Examination
Generated On: 26 Nov 2020 09:24:33

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

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

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US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33

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

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

FDA-CBER-2022-1614-5939373

US3432334
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 09:24:33

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

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US3432334
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:24:33

What was the date of randomization? *(dd MMM yyyy)*	28 AUG 2020
What was the participant's randomization number?	109372
In what Cohort was the participant enrolled?	>=18 and <65 years and not at risk ■ >=18 and <65 years and at risk ☐ >=65 years ☐

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

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

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Height	ND - Not Done
Weight	ND - Not Done

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US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33

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)*	28 AUG 2020
Time of assessment *(00:00-23:59)*	9:37 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 9:37
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	48 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

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US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33

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)*	28 AUG 2020
Time of assessment *(00:00-23:59)*	11:19 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 11:19
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	53 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	87 mmHg
Diastolic Blood Pressure units	MMHG

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US3432334
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 26 Nov 2020 09:24:33

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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US3432334
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:24:33

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	28 AUG 2020
What was the treatment time? *(00:00-23:59)*	10:41 (24 HR)
Treatment Date and Time (derived)	28 AUG 2020 10:41
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	28 AUG 2020
Collection time *(00:00-23:59)*	9:45 (24 HR)
Collection date and time (derived)	28 AUG 2020 9:45

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Collection date *(dd MMM yyyy)*			28 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	9:56	28 AUG 2020 9:56
Nasopharyngeal Swab 2	No		

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

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US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:24:33

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**	98.0 °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	28 AUG 2020 11:23
PC Open Date & Time	28 AUG 2020 11:01
PC Close Date & Time	28 AUG 2020 13:31

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US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:24:33

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	29 AUG 2020 10:09
PC Open Date & Time	28 AUG 2020 14:26
PC Close Date & Time	29 AUG 2020 11:59

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US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:24:33

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**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

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US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:24:33

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.0 °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	30 AUG 2020 17:49
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

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US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:24:33

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	31 AUG 2020 18:36
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

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US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:24:33

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	01 SEP 2020 18:15
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

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US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:24:33

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**	94.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	02 SEP 2020 18:06
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

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US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:24:33

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	03 SEP 2020 17:12
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-5939391

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:24:33

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	28 AUG 2020 11:24
PC Open Date & Time	28 AUG 2020 11:01
PC Close Date & Time	28 AUG 2020 13:31

FDA-CBER-2022-1614-5939392

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:24:33

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	29 AUG 2020 10:10
PC Open Date & Time	28 AUG 2020 14:26
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-5939393

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:24:33

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 ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

FDA-CBER-2022-1614-5939394

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:24:33

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	30 AUG 2020 17:49
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

FDA-CBER-2022-1614-5939395

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:24:33

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	31 AUG 2020 18:37
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

FDA-CBER-2022-1614-5939396

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:24:33

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	01 SEP 2020 18:15
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

FDA-CBER-2022-1614-5939397

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:24:33

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	02 SEP 2020 18:06
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

FDA-CBER-2022-1614-5939398

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:24:33

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	03 SEP 2020 17:11
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-5939399

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-2022-1614-5939400

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:24:33

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	28 AUG 2020 11:24
PC Open Date & Time	28 AUG 2020 11:01
PC Close Date & Time	28 AUG 2020 13:31

FDA-CBER-2022-1614-5939401

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-2022-1614-5939402

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:24:33

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ● Yes ○
PC Time stamp	29 AUG 2020 10:10
PC Open Date & Time	28 AUG 2020 14:26
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-5939403

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:24:33

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-2022-1614-5939404

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

FDA-CBER-2022-1614-5939405

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:24:33

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-2022-1614-5939406

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:24:33

	Yes ☐
PC Time stamp	30 AUG 2020 17:49
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

FDA-CBER-2022-1614-5939407

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:24:33

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-2022-1614-5939408

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:24:33

	Yes ☐
PC Time stamp	31 AUG 2020 18:38
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

FDA-CBER-2022-1614-5939409

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:24:33

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-2022-1614-5939410

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:24:33

	Yes ☐
PC Time stamp	01 SEP 2020 18:15
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

FDA-CBER-2022-1614-5939411

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-2022-1614-5939412

	Yes ☐
PC Time stamp	02 SEP 2020 18:07
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:24:33

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-2022-1614-5939414

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:24:33

	Yes ☐
PC Time stamp	03 SEP 2020 17:11
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-5939415

US3432334
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	4 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

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

FDA-CBER-2022-1614-5939417

US3432334
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33

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

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

FDA-CBER-2022-1614-5939419

US3432334
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	18 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-5939420

US3432334
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939421

US3432334
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939422

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	28 SEP 2020
Time of assessment *(00:00-23:59)*	14:28 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 14:28
Temperature *(xxx.x)*	97.7 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	INFRARED
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	66 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-5939423

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-2022-1614-5939424

US3432334
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 09:24:33

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

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

FDA-CBER-2022-1614-5939425

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-2022-1614-5939426

US3432334
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:24:33

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	28 SEP 2020
Collection time *(00:00-23:59)*	14:40 (24 HR)
Collection date and time (derived)	28 SEP 2020 14:40

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Collection date *(dd MMM yyyy)*

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

US3432334
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939429

US3432334
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	5 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-2022-1614-5939430

US3432334
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939431

US3432334
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	12 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-2022-1614-5939432

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

FDA-CBER-2022-1614-5939433

US3432334
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	19 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-2022-1614-5939434

US3432334
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939435

US3432334
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:24:33

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-5939436

US3432334
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	28 OCT 2020
Time of assessment *(00:00-23:59)*	11:25 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 11:25
Temperature *(xxx.x)*	97.3 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	65 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-5939437

US3432334
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 09:24:33

Was the physical examination performed? Yes ☐ No ■

Date of examination *(dd MMM yyyy)* _____

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

FDA-CBER-2022-1614-5939438

US3432334
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:24:33

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	28 OCT 2020
Collection time *(00:00-23:59)*	11:32 (24 HR)
Collection date and time (derived)	28 OCT 2020 11:32

FDA-CBER-2022-1614-5939439

US3432334
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939440

US3432334
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☑ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☑
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☑
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 OCT 2020 12:36:56
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

FDA-CBER-2022-1614-5939441

US3432334
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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	06 NOV 2020 12:00:56
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

FDA-CBER-2022-1614-5939442

US3432334
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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	11 NOV 2020 05:44:51
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

FDA-CBER-2022-1614-5939443

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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-2022-1614-5939444

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939445

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-2022-1614-5939446

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

FDA-CBER-2022-1614-5939447

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

FDA-CBER-2022-1614-5939449

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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-2022-1614-5939450

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

FDA-CBER-2022-1614-5939451

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 14:45:36
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

FDA-CBER-2022-1614-5939452

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-2022-1614-5939453

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939454

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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-2022-1614-5939455

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

FDA-CBER-2022-1614-5939456

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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-2022-1614-5939457

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939458

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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-2022-1614-5939459

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939460

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-5939461

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

FDA-CBER-2022-1614-5939462

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-2022-1614-5939463

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939464

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939466

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939468

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939470

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-2022-1614-5939471

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939472

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939474

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939476

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939478

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-2022-1614-5939479

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939480

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939482

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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-2022-1614-5939483

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939484

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939486

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-2022-1614-5939487

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939488

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 ☐

FDA-CBER-2022-1614-5939489

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939490

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-2022-1614-5939491

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939492

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-5939493

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939494

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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-2022-1614-5939495

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939496

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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-2022-1614-5939497

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939498

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-5939499

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939500

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939502

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939504

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939506

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939508

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939510

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 ☐

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

FDA-CBER-2022-1614-5939512

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939514

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939516

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939518

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939520

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939522

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939524

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939526

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-2022-1614-5939527

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939528

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939530

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939532

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939534

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939536

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-5939537

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939538

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939540

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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-2022-1614-5939541

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939542

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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-2022-1614-5939543

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939544

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939546

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939548

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939550

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939552

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939554

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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 ☐

FDA-CBER-2022-1614-5939555

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939556

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939558

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

FDA-CBER-2022-1614-5939559

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939560

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939562

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939564

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-5939565

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939566

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939568

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939570

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939572

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939574

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939576

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-2022-1614-5939577

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939578

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939580

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-2022-1614-5939581

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939582

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939584

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939586

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939588

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-2022-1614-5939589

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939590

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939592

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-2022-1614-5939593

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939594

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

TIMEPOINT	DAY 593
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-5939595

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939596

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939598

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939600

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 MAY 2022 00:01
Patient Cloud Close Date & Time	05 MAY 2022 23:59

FDA-CBER-2022-1614-5939602

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-5939603

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939604

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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-2022-1614-5939605

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

FDA-CBER-2022-1614-5939606

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939608

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939610

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939612

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939614

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 ☐

FDA-CBER-2022-1614-5939615

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939616

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939618

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939620

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939622

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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-2022-1614-5939623

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939624

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939626

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939628

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939630

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-2022-1614-5939631

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939632

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939634

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 ☐

FDA-CBER-2022-1614-5939635

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939636

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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-2022-1614-5939637

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939638

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939640

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939642

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939644

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939646

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939648

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939650

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 ☐

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

FDA-CBER-2022-1614-5939652

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 ☐

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33

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

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US3432334
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33

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

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

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US3432334
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33

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	

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

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US3432334
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 26 Nov 2020 09:24:33

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐ Clinical Visit - Unscheduled ☐ Safety Call ☐ Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐ No ☐

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Generate Next COVID-19 Assessment	Yes ☐ No ☐

FDA-CBER-2022-1614-5939660

US3432334
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 26 Nov 2020 09:24:33

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

If Yes, enter details on the Adverse Events form.

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US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33

AEID	
Adverse event	SARS-COV-2 INFECTION (ASYMPTOMATIC)
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)*	16 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)*	26 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	

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

FDA-CBER-2022-1614-5939663

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 26 Nov 2020 09:24:33

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

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

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US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:24:33

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

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

FDA-CBER-2022-1614-5939666

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:24:33

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

FDA-CBER-2022-1614-5939667

	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)*	5 OCT 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

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Name of Medication	HEPATITIS B VACCINE
Prophylaxis	Yes ■ No ☐
Indication	HEPATITIS B PROPHYLAXIS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	INJECTION
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ■

	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	05 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	5 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-2022-1614-5939670

US3432334
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 26 Nov 2020 09:24:33

Were any concomitant procedures performed?	Yes ☐
	No ☐

If yes, please complete Concomitant Procedures form.

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US3432334
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 26 Nov 2020 09:24:33

Date of dosing discontinuation (dd MMM yyyy)	26 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-2022-1614-5939672

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 ☐

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Audit

US3432334 (Prod: Brigham and Womens Hospital)

US3432334
Form: Participant Creation
Generated On: 26 Nov 2020 09:24:33
Participant ID

Audit	User	Time (GMT)
User entered 'US3432334'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:34:46

FDA-CBER-2022-1614-5939675

US3432334
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 09:24:33
Was this visit performed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:57:10
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:22:46

FDA-CBER-2022-1614-5939676

US3432334
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 09:24:33
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:57:10
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:34:47

FDA-CBER-2022-1614-5939677

US3432334
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 09:24:33
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:57:10
User entered 'Clinic (Clinic)'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:22:46

FDA-CBER-2022-1614-5939678

US3432334
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 09:24:33
Folder OID

Audit	User	Time (GMT)
User entered 'SCRN'	System	28 Aug 2020 14:22:46

FDA-CBER-2022-1614-5939679

US3432334
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:24:33
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered (b) (6) 1991'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:34:48

FDA-CBER-2022-1614-5939680

US3432334
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:24:33
Age

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered '29'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

FDA-CBER-2022-1614-5939681

US3432334
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:24:33
Age Units

Audit	User	Time (GMT)
User entered 'YEARS'	System	28 Aug 2020 15:46:27

FDA-CBER-2022-1614-5939682

US3432334
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:24:33
Age (Derived)

Audit	User	Time (GMT)
User entered '29'	System	28 Aug 2020 14:23:01

FDA-CBER-2022-1614-5939683

US3432334
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:24:33
Sex

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered 'Male (M)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

FDA-CBER-2022-1614-5939684

US3432334
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:24:33
Ethnicity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

FDA-CBER-2022-1614-5939685

US3432334
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:24:33
White

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered '1'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

FDA-CBER-2022-1614-5939686

US3432334
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:24:33
Black

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

FDA-CBER-2022-1614-5939687

US3432334
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:24:33
Asian

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

FDA-CBER-2022-1614-5939688

US3432334
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:24:33
American Indian or Alaska Native

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

FDA-CBER-2022-1614-5939689

US3432334
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:24:33
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

FDA-CBER-2022-1614-5939690

US3432334
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:24:33
Other

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

FDA-CBER-2022-1614-5939691

US3432334
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:24:33
If race is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

FDA-CBER-2022-1614-5939692

US3432334
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:24:33
Unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

FDA-CBER-2022-1614-5939693

US3432334
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:24:33
Not reported

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

FDA-CBER-2022-1614-5939694

US3432334
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:24:33
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:47
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:01

FDA-CBER-2022-1614-5939695

US3432334
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:24:33
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	28 Aug 2020 14:23:01

FDA-CBER-2022-1614-5939696

US3432334
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:24:33
Year of Informed Consent (derived)

Audit	User	Time (GMT)
User entered '2020'	System	28 Aug 2020 14:23:01

FDA-CBER-2022-1614-5939697

US3432334
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:24:33
Protocol Version

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:47
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 19:18:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 19:18:28
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 19:18:28
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 14:23:01
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:01

FDA-CBER-2022-1614-5939698

US3432334
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:24:33
Was participant enrolled in the study?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:47
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:01

FDA-CBER-2022-1614-5939699

US3432334
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:24:33
If No, indicate reason for screen fail

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:47
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:01

FDA-CBER-2022-1614-5939700

US3432334
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:24:33
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:47
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:01

FDA-CBER-2022-1614-5939701

US3432334
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:24:33
Was this participant screened previously?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:47
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:01

FDA-CBER-2022-1614-5939702

US3432334
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:24:33
If Yes, previous participant number

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:47
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:34:47

FDA-CBER-2022-1614-5939703

US3432334
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:24:33
Enrollment Trigger

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 14:23:08

FDA-CBER-2022-1614-5939704

US3432334
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 26 Nov 2020 09:24:33
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:01:07
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:08

FDA-CBER-2022-1614-5939705

US3432334
Folder: Screening
Form: Medical History Summary
Generated On: 26 Nov 2020 09:24:33
Were any significant conditions reported?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:01:09
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:47:03

FDA-CBER-2022-1614-5939706

US3432334
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:24:33
Condition

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:07
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:48:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:48:47
Data point term sent to Coder	System	28 Aug 2020 15:48:08
User entered 'Mild asthma'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:47:38

FDA-CBER-2022-1614-5939707

US3432334
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:24:33
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:07
User entered 'un UNK 2018'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:47:38

FDA-CBER-2022-1614-5939708

US3432334
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:24:33
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:07
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:47:38

FDA-CBER-2022-1614-5939709

US3432334
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:24:33
Condition ongoing at study entry

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:07
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:47:38

FDA-CBER-2022-1614-5939710

US3432334
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:24:33
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:07
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:47:38

FDA-CBER-2022-1614-5939711

US3432334
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:24:33
Stop date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:07
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:47:38

FDA-CBER-2022-1614-5939712

US3432334
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:24:33
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	28 Aug 2020 15:47:38

FDA-CBER-2022-1614-5939713

US3432334
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:24:33
Start Year (derived)

Audit	User	Time (GMT)
User entered '2018'	System	28 Aug 2020 15:47:38

FDA-CBER-2022-1614-5939714

US3432334
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:24:33
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 15:47:38

FDA-CBER-2022-1614-5939715

US3432334
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:24:33
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 15:47:38

FDA-CBER-2022-1614-5939716

US3432334
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Were vital signs assessed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53

FDA-CBER-2022-1614-5939717

US3432334
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53

FDA-CBER-2022-1614-5939718

US3432334
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered '09:37' reason for change: Data Entry Error	Julia Klopfer (b) (4) (b) (4)	19 Oct 2020 23:21:30
User entered '9:37'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53

FDA-CBER-2022-1614-5939719

US3432334
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '28 Aug 2020 09:37'	System	19 Oct 2020 23:21:30
User entered '28 Aug 2020 9:37'	System	28 Aug 2020 15:48:53

FDA-CBER-2022-1614-5939720

US3432334
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Height *(xxx.x)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered '170.5' cm	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53
DataPoint set to visible.	System	28 Aug 2020 14:23:08

FDA-CBER-2022-1614-5939721

US3432334
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Weight *(xxx.x)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered '72.5' kg	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53
DataPoint set to visible.	System	28 Aug 2020 14:23:08

FDA-CBER-2022-1614-5939722

US3432334
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
BMI *(xxx.x)*

Audit	User	Time (GMT)
User entered '24.93959'	System	28 Aug 2020 15:48:53
DataPoint set to visible.	System	28 Aug 2020 14:23:08

FDA-CBER-2022-1614-5939723

US3432334
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
BMI units

Audit	User	Time (GMT)
User entered 'kg/m2'	System	28 Aug 2020 15:48:53
DataPoint set to visible.	System	28 Aug 2020 14:23:08

FDA-CBER-2022-1614-5939724

US3432334
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53

FDA-CBER-2022-1614-5939725

US3432334
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Route of measurement

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53

FDA-CBER-2022-1614-5939726

US3432334
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
If Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53

FDA-CBER-2022-1614-5939727

US3432334
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Pulse *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53

FDA-CBER-2022-1614-5939728

US3432334
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Aug 2020 15:48:53

FDA-CBER-2022-1614-5939729

US3432334
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53

FDA-CBER-2022-1614-5939730

US3432334
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Aug 2020 15:48:53

FDA-CBER-2022-1614-5939731

US3432334
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53

FDA-CBER-2022-1614-5939732

US3432334
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 15:48:53

FDA-CBER-2022-1614-5939733

US3432334
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53

FDA-CBER-2022-1614-5939734

US3432334
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 15:48:53

FDA-CBER-2022-1614-5939735

US3432334
Folder: Screening
Form: Physical Examination
Generated On: 26 Nov 2020 09:24:33
Was the physical examination performed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:36
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:27

FDA-CBER-2022-1614-5939736

US3432334
Folder: Screening
Form: Physical Examination
Generated On: 26 Nov 2020 09:24:33
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:36
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:27

FDA-CBER-2022-1614-5939737

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

FDA-CBER-2022-1614-5939738

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

FDA-CBER-2022-1614-5939739

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

FDA-CBER-2022-1614-5939740

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

FDA-CBER-2022-1614-5939741

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

FDA-CBER-2022-1614-5939742

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

FDA-CBER-2022-1614-5939743

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

FDA-CBER-2022-1614-5939744

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

FDA-CBER-2022-1614-5939745

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

FDA-CBER-2022-1614-5939746

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

FDA-CBER-2022-1614-5939747

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

FDA-CBER-2022-1614-5939748

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
Other

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

FDA-CBER-2022-1614-5939749

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
Specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

FDA-CBER-2022-1614-5939750

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

FDA-CBER-2022-1614-5939751

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

FDA-CBER-2022-1614-5939752

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered '1'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

FDA-CBER-2022-1614-5939754

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

FDA-CBER-2022-1614-5939755

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

FDA-CBER-2022-1614-5939756

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
Other

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

FDA-CBER-2022-1614-5939757

US3432334
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:24:33
Specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

FDA-CBER-2022-1614-5939758

US3432334
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 09:24:33
Was this visit performed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:48
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:18

FDA-CBER-2022-1614-5939759

US3432334
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 09:24:33
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:48
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:18

FDA-CBER-2022-1614-5939760

US3432334
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 09:24:33
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:48
User entered 'Clinic (Clinic)'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:18

FDA-CBER-2022-1614-5939761

US3432334
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 09:24:33
Folder OID

Audit	User	Time (GMT)
User entered 'VISIT1'	System	28 Aug 2020 14:23:18

FDA-CBER-2022-1614-5939762

US3432334
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:24:33
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:58
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:49:43

FDA-CBER-2022-1614-5939763

US3432334
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:24:33
What was the participant's randomization number?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:58
User entered '109372'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:49:43

FDA-CBER-2022-1614-5939764

US3432334
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:24:33
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:58
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:49:43

FDA-CBER-2022-1614-5939765

US3432334
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:24:33
Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:58
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:50:31

FDA-CBER-2022-1614-5939766

US3432334
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:24:33

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:58
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:50:31

FDA-CBER-2022-1614-5939767

US3432334
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:24:33
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:58
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:50:31

FDA-CBER-2022-1614-5939768

US3432334
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:24:33
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:58
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:50:31

FDA-CBER-2022-1614-5939769

US3432334
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:24:33
Liver Disease

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:58
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:50:31

FDA-CBER-2022-1614-5939770

US3432334
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:24:33
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:58
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	19 Oct 2020 23:22:38
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:23:58
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:23:57

FDA-CBER-2022-1614-5939771

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 09:24:33
Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939772

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 09:24:33
Weight

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939773

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 09:24:33
Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939774

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 09:24:33
Weight

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939775

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939776

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Were vital signs assessed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939777

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939778

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '9:37'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939779

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '28 Aug 2020 9:37'	System	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939780

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '36.6' C	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939781

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Route of measurement

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered 'Oral (Oral)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939782

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
If Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939783

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Pulse *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '48'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939784

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939785

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '16'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939786

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939787

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '141'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939788

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939789

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '80'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939790

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939791

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 09:24:33
Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939792

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 09:24:33
Weight

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939793

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939794

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Were vital signs assessed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939795

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939796

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '11:19'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939797

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:19'	System	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939798

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '36.7' C	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939799

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Route of measurement

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered 'Oral (Oral)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939800

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
If Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939801

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Pulse *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '53'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939802

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939803

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '16'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939804

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939805

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '122'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939806

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939807

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '87'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939808

US3432334
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 15:52:49

FDA-CBER-2022-1614-5939809

US3432334
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 26 Nov 2020 09:24:33
Was the physical examination performed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:23
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	14 Sep 2020 12:14:37
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	28 Aug 2020 14:23:33
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:33

FDA-CBER-2022-1614-5939810

US3432334
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 26 Nov 2020 09:24:33
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:23
User entered empty; reason for change Per Query Resolution	Jessica Cauley (b) (4) (b) (4)	14 Sep 2020 12:14:37
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:33

FDA-CBER-2022-1614-5939811

US3432334
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:24:33
Was study treatment given?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:38
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939812

US3432334
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:24:33
If No, reason not given

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:38
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939813

US3432334
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:24:33
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:38
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939814

US3432334
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:24:33
What was the study treatment?

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939815

US3432334
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:24:33
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:38
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939816

US3432334
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:24:33
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:38
User entered '10:41'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939817

US3432334
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:24:33
Treatment Date and Time (derived)

Audit	User	Time (GMT)
User entered '28 Aug 2020 10:41'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939818

US3432334
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:24:33
Which arm was used to give treatment?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:38
User entered 'Left Arm (LEFT ARM)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939819

US3432334
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:24:33
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:38
User entered 'ONCE'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939820

US3432334
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:24:33
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939821

US3432334
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:24:33
Was the sample collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:55
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 18:57:58

FDA-CBER-2022-1614-5939822

US3432334
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:24:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:55
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	28 Aug 2020 18:57:58

FDA-CBER-2022-1614-5939823

US3432334
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:24:33
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:55
User entered '9:45'	Phoebe Cunningham (b) (4)	28 Aug 2020 18:57:58

FDA-CBER-2022-1614-5939824

US3432334
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:24:33
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '28 Aug 2020 9:45'	System	28 Aug 2020 18:57:58

FDA-CBER-2022-1614-5939825

US3432334
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 26 Nov 2020 09:24:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:59
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	28 Aug 2020 18:58:13

FDA-CBER-2022-1614-5939826

US3432334
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:24:33
Lab Test

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Phoebe Cunningham (b) (4)	28 Aug 2020 18:58:13

FDA-CBER-2022-1614-5939827

US3432334
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:24:33
Was the sample collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 18:58:13

FDA-CBER-2022-1614-5939828

US3432334
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:24:33
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:59
User entered '9:56'	Phoebe Cunningham (b) (4)	28 Aug 2020 18:58:13

FDA-CBER-2022-1614-5939829

US3432334
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:24:33
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '28 Aug 2020 9:56'	System	28 Aug 2020 18:58:13

FDA-CBER-2022-1614-5939830

US3432334
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:24:33
Lab Test

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Phoebe Cunningham (b) (4)	28 Aug 2020 18:58:13

FDA-CBER-2022-1614-5939831

US3432334
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:24:33
Was the sample collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 18:58:13

FDA-CBER-2022-1614-5939832

US3432334
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:24:33
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:59
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 18:58:13

FDA-CBER-2022-1614-5939833

US3432334
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:24:33
Collection date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 18:58:13

FDA-CBER-2022-1614-5939834

US3432334
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 26 Nov 2020 09:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:01
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:55

FDA-CBER-2022-1614-5939835

US3432334
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 26 Nov 2020 09:24:33
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 15:52:55

FDA-CBER-2022-1614-5939836

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939837

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:23:36', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'ff52a4b2-6fa3-4f62-baff-ebe91e24c1ef'	System	28 Aug 2020 15:23:50
User entered 'Yes (Y)'	System	28 Aug 2020 15:23:50

FDA-CBER-2022-1614-5939838

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:23:39', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'ff52a4b2-6fa3-4f62-baff-ebe91e24c1ef'	System	28 Aug 2020 15:23:50
User entered '98.0'	System	28 Aug 2020 15:23:50

FDA-CBER-2022-1614-5939839

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:23:44', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'ff52a4b2-6fa3-4f62-baff-ebe91e24c1ef'	System	28 Aug 2020 15:23:50
User entered 'No (N)'	System	28 Aug 2020 15:23:50

FDA-CBER-2022-1614-5939840

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:23:48', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'ff52a4b2-6fa3-4f62-baff-ebe91e24c1ef'	System	28 Aug 2020 15:23:50
User entered '28 Aug 2020 11:23'	System	28 Aug 2020 15:23:50

FDA-CBER-2022-1614-5939841

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:01'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939842

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 13:31'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939843

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939844

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T08:39:34', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '19b3f324-f6bf-40a3-b968-bd926d4dcdd5'	System	29 Aug 2020 14:09:33
User entered 'Yes (Y)'	System	29 Aug 2020 14:09:33

FDA-CBER-2022-1614-5939845

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:09:24', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '19b3f324-f6bf-40a3-b968-bd926d4dcdd5'	System	29 Aug 2020 14:09:33
User entered '97.7'	System	29 Aug 2020 14:09:33

FDA-CBER-2022-1614-5939846

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:09:27', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '19b3f324-f6bf-40a3-b968-bd926d4dcdd5'	System	29 Aug 2020 14:09:33
User entered 'No (N)'	System	29 Aug 2020 14:09:33

FDA-CBER-2022-1614-5939847

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:09:31', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '19b3f324-f6bf-40a3-b968-bd926d4dcdd5'	System	29 Aug 2020 14:09:33
User entered '29 Aug 2020 10:09'	System	29 Aug 2020 14:09:33

FDA-CBER-2022-1614-5939848

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 14:26'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939849

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939850

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 2'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939851

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939852

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939853

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 3'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939854

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:48:50', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '90f7d1ba-690a-408b-9db4-b3125314a8ed'	System	30 Aug 2020 21:49:02
User entered 'Yes (Y)'	System	30 Aug 2020 21:49:02

FDA-CBER-2022-1614-5939855

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:48:56', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '90f7d1ba-690a-408b-9db4-b3125314a8ed'	System	30 Aug 2020 21:49:02
User entered '96.0'	System	30 Aug 2020 21:49:02

FDA-CBER-2022-1614-5939856

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:48:58', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '90f7d1ba-690a-408b-9db4-b3125314a8ed'	System	30 Aug 2020 21:49:02
User entered 'No (N)'	System	30 Aug 2020 21:49:02

FDA-CBER-2022-1614-5939857

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:24:33
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:01', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '90f7d1ba-690a-408b-9db4-b3125314a8ed'	System	30 Aug 2020 21:49:02
User entered '30 Aug 2020 17:49'	System	30 Aug 2020 21:49:02

FDA-CBER-2022-1614-5939858

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939859

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939860

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 4'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939861

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:36:13', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'd190ae70-5e3e-4b2c-ba9c-8324b27344af'	System	31 Aug 2020 22:36:25
User entered 'Yes (Y)'	System	31 Aug 2020 22:36:25

FDA-CBER-2022-1614-5939862

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:36:17', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'd190ae70-5e3e-4b2c-ba9c-8324b27344af'	System	31 Aug 2020 22:36:25
User entered '96.1'	System	31 Aug 2020 22:36:25

FDA-CBER-2022-1614-5939863

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:36:19', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'd190ae70-5e3e-4b2c-ba9c-8324b27344af'	System	31 Aug 2020 22:36:25
User entered 'No (N)'	System	31 Aug 2020 22:36:25

FDA-CBER-2022-1614-5939864

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:24:33
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:36:22', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'd190ae70-5e3e-4b2c-ba9c-8324b27344af'	System	31 Aug 2020 22:36:25
User entered '31 Aug 2020 18:36'	System	31 Aug 2020 22:36:25

FDA-CBER-2022-1614-5939865

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939866

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939867

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 5'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939868

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:42', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9823d05-4bb0-460a-886f-f1f7d2d0d2ee'	System	01 Sep 2020 22:15:52
User entered 'Yes (Y)'	System	01 Sep 2020 22:15:52

FDA-CBER-2022-1614-5939869

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:46', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9823d05-4bb0-460a-886f-f1f7d2d0d2ee'	System	01 Sep 2020 22:15:52
User entered '96.4'	System	01 Sep 2020 22:15:52

FDA-CBER-2022-1614-5939870

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:48', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9823d05-4bb0-460a-886f-f1f7d2d0d2ee'	System	01 Sep 2020 22:15:52
User entered 'No (N)'	System	01 Sep 2020 22:15:52

FDA-CBER-2022-1614-5939871

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:24:33
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:50', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9823d05-4bb0-460a-886f-f1f7d2d0d2ee'	System	01 Sep 2020 22:15:52
User entered '01 Sep 2020 18:15'	System	01 Sep 2020 22:15:52

FDA-CBER-2022-1614-5939872

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939873

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939874

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 6'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939875

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:02:08', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '07fefb70-405b-4634-8682-ee99565df9c5'	System	02 Sep 2020 22:06:52
User entered 'Yes (Y)'	System	02 Sep 2020 22:06:52

FDA-CBER-2022-1614-5939876

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:06:46', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '07fefb70-405b-4634-8682-ee99565df9c5'	System	02 Sep 2020 22:06:52
User entered '94.7'	System	02 Sep 2020 22:06:52

FDA-CBER-2022-1614-5939877

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:06:48', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '07fefb70-405b-4634-8682-ee99565df9c5'	System	02 Sep 2020 22:06:52
User entered 'No (N)'	System	02 Sep 2020 22:06:52

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:24:33
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:06:50', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '07fefb70-405b-4634-8682-ee99565df9c5'	System	02 Sep 2020 22:06:52
User entered '02 Sep 2020 18:06'	System	02 Sep 2020 22:06:52

FDA-CBER-2022-1614-5939879

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939880

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939881

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 7'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939882

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:33', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9c8af5a2-966a-4640-ac36-fa8242e968c9'	System	03 Sep 2020 21:12:09
User entered 'Yes (Y)'	System	03 Sep 2020 21:12:09

FDA-CBER-2022-1614-5939883

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:12:02', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9c8af5a2-966a-4640-ac36-fa8242e968c9'	System	03 Sep 2020 21:12:09
User entered '96.9'	System	03 Sep 2020 21:12:09

FDA-CBER-2022-1614-5939884

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:12:04', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9c8af5a2-966a-4640-ac36-fa8242e968c9'	System	03 Sep 2020 21:12:09
User entered 'No (N)'	System	03 Sep 2020 21:12:09

FDA-CBER-2022-1614-5939885

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:24:33
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:12:07', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9c8af5a2-966a-4640-ac36-fa8242e968c9'	System	03 Sep 2020 21:12:09
User entered '03 Sep 2020 17:12'	System	03 Sep 2020 21:12:09

FDA-CBER-2022-1614-5939886

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939887

US3432334
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939888

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939889

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:23:55', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '73c1ce4e-7e99-4a21-8333-828d58bc2660'	System	28 Aug 2020 15:24:14
User entered 'None (1)'	System	28 Aug 2020 15:24:14

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:01', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '73c1ce4e-7e99-4a21-8333-828d58bc2660'	System	28 Aug 2020 15:24:14
User entered 'No (N)'	System	28 Aug 2020 15:24:14

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:04', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '73c1ce4e-7e99-4a21-8333-828d58bc2660'	System	28 Aug 2020 15:24:14
User entered 'No (N)'	System	28 Aug 2020 15:24:14

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:08', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '73c1ce4e-7e99-4a21-8333-828d58bc2660'	System	28 Aug 2020 15:24:14
User entered 'None (1)'	System	28 Aug 2020 15:24:14

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:11', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '73c1ce4e-7e99-4a21-8333-828d58bc2660'	System	28 Aug 2020 15:24:14
User entered '28 Aug 2020 11:24'	System	28 Aug 2020 15:24:14

FDA-CBER-2022-1614-5939894

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:01'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939895

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 13:31'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939896

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939897

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:09:47', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '65fdc107-aa93-4686-a2c7-0aa013845bbf'	System	29 Aug 2020 14:10:05
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 14:10:05

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:09:51', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '65fdc107-aa93-4686-a2c7-0aa013845bbf'	System	29 Aug 2020 14:10:05
User entered 'No (N)'	System	29 Aug 2020 14:10:05

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:09:57', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '65fdc107-aa93-4686-a2c7-0aa013845bbf'	System	29 Aug 2020 14:10:05
User entered 'No (N)'	System	29 Aug 2020 14:10:05

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:10:00', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '65fdc107-aa93-4686-a2c7-0aa013845bbf'	System	29 Aug 2020 14:10:05
User entered 'None (1)'	System	29 Aug 2020 14:10:05

FDA-CBER-2022-1614-5939901

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:10:03', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '65fdc107-aa93-4686-a2c7-0aa013845bbf'	System	29 Aug 2020 14:10:05
User entered '29 Aug 2020 10:10'	System	29 Aug 2020 14:10:05

FDA-CBER-2022-1614-5939902

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 14:26'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939903

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939904

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 2'	System	28 Aug 2020 15:13:20

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939906

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939907

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 3'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939908

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:06', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'c28e2278-5fdc-40ac-aa4f-dc432fce8af9'	System	30 Aug 2020 21:49:24
User entered 'None (1)'	System	30 Aug 2020 21:49:24

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:09', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'c28e2278-5fdc-40ac-aa4f-dc432fce8af9'	System	30 Aug 2020 21:49:24
User entered 'No (N)'	System	30 Aug 2020 21:49:24

FDA-CBER-2022-1614-5939910

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:15', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'c28e2278-5fdc-40ac-aa4f-dc432fce8af9'	System	30 Aug 2020 21:49:24
User entered 'No (N)'	System	30 Aug 2020 21:49:24

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:17', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'c28e2278-5fdc-40ac-aa4f-dc432fce8af9'	System	30 Aug 2020 21:49:24
User entered 'None (1)'	System	30 Aug 2020 21:49:24

FDA-CBER-2022-1614-5939912

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:24:33
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:19', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'c28e2278-5fdc-40ac-aa4f-dc432fce8af9'	System	30 Aug 2020 21:49:24
User entered '30 Aug 2020 17:49'	System	30 Aug 2020 21:49:24

FDA-CBER-2022-1614-5939913

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939914

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939915

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 4'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939916

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:36:30', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '4049a8a4-f9a5-4185-9dd1-3775b8d2dba4'	System	31 Aug 2020 22:37:50
User entered 'None (1)'	System	31 Aug 2020 22:37:50

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:37:12', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '4049a8a4-f9a5-4185-9dd1-3775b8d2dba4'	System	31 Aug 2020 22:37:50
User entered 'No (N)'	System	31 Aug 2020 22:37:50

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:37:34', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '4049a8a4-f9a5-4185-9dd1-3775b8d2dba4'	System	31 Aug 2020 22:37:50
User entered 'No (N)'	System	31 Aug 2020 22:37:50

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:37:36', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '4049a8a4-f9a5-4185-9dd1-3775b8d2dba4'	System	31 Aug 2020 22:37:50
User entered 'None (1)'	System	31 Aug 2020 22:37:50

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:24:33
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:37:45', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '4049a8a4-f9a5-4185-9dd1-3775b8d2dba4'	System	31 Aug 2020 22:37:50
User entered '31 Aug 2020 18:37'	System	31 Aug 2020 22:37:50

FDA-CBER-2022-1614-5939921

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939922

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939923

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 5'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939924

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:16', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '4a34c94a-1085-4c6e-ba7c-0ec10bac909a'	System	01 Sep 2020 22:15:26
User entered 'None (1)'	System	01 Sep 2020 22:15:26

FDA-CBER-2022-1614-5939925

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:17', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '4a34c94a-1085-4c6e-ba7c-0ec10bac909a'	System	01 Sep 2020 22:15:26
User entered 'No (N)'	System	01 Sep 2020 22:15:26

FDA-CBER-2022-1614-5939926

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:19', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '4a34c94a-1085-4c6e-ba7c-0ec10bac909a'	System	01 Sep 2020 22:15:26
User entered 'No (N)'	System	01 Sep 2020 22:15:26

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:21', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '4a34c94a-1085-4c6e-ba7c-0ec10bac909a'	System	01 Sep 2020 22:15:26
User entered 'None (1)'	System	01 Sep 2020 22:15:26

FDA-CBER-2022-1614-5939928

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:24:33
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:22', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '4a34c94a-1085-4c6e-ba7c-0ec10bac909a'	System	01 Sep 2020 22:15:26
User entered '01 Sep 2020 18:15'	System	01 Sep 2020 22:15:26

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939930

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939931

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 6'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939932

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:06:53', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9e5afb97-b25c-43c1-9203-a88d38b458ec'	System	02 Sep 2020 22:07:04
User entered 'None (1)'	System	02 Sep 2020 22:07:04

FDA-CBER-2022-1614-5939933

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:06:55', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9e5afb97-b25c-43c1-9203-a88d38b458ec'	System	02 Sep 2020 22:07:04
User entered 'No (N)'	System	02 Sep 2020 22:07:04

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:06:56', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9e5afb97-b25c-43c1-9203-a88d38b458ec'	System	02 Sep 2020 22:07:04
User entered 'No (N)'	System	02 Sep 2020 22:07:04

FDA-CBER-2022-1614-5939935

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:06:58', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9e5afb97-b25c-43c1-9203-a88d38b458ec'	System	02 Sep 2020 22:07:04
User entered 'None (1)'	System	02 Sep 2020 22:07:04

FDA-CBER-2022-1614-5939936

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:24:33
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:06:59', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9e5afb97-b25c-43c1-9203-a88d38b458ec'	System	02 Sep 2020 22:07:04
User entered '02 Sep 2020 18:06'	System	02 Sep 2020 22:07:04

FDA-CBER-2022-1614-5939937

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939938

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939939

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 7'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939940

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:19', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'de63bf0e-c69e-453b-bf3c-869543f50e64'	System	03 Sep 2020 21:11:32
User entered 'None (1)'	System	03 Sep 2020 21:11:32

FDA-CBER-2022-1614-5939941

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:22', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'de63bf0e-c69e-453b-bf3c-869543f50e64'	System	03 Sep 2020 21:11:32
User entered 'No (N)'	System	03 Sep 2020 21:11:32

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:24', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'de63bf0e-c69e-453b-bf3c-869543f50e64'	System	03 Sep 2020 21:11:32
User entered 'No (N)'	System	03 Sep 2020 21:11:32

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:25', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'de63bf0e-c69e-453b-bf3c-869543f50e64'	System	03 Sep 2020 21:11:32
User entered 'None (1)'	System	03 Sep 2020 21:11:32

FDA-CBER-2022-1614-5939944

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:24:33
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:28', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'de63bf0e-c69e-453b-bf3c-869543f50e64'	System	03 Sep 2020 21:11:32
User entered '03 Sep 2020 17:11'	System	03 Sep 2020 21:11:32

FDA-CBER-2022-1614-5939945

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939946

US3432334
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939947

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939948

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:17', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9ae7b2c-1b28-4f59-bc04-1be2c29ab24d'	System	28 Aug 2020 15:24:34
User entered 'None (0)'	System	28 Aug 2020 15:24:34

FDA-CBER-2022-1614-5939949

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:18', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9ae7b2c-1b28-4f59-bc04-1be2c29ab24d'	System	28 Aug 2020 15:24:34
User entered 'None (0)'	System	28 Aug 2020 15:24:34

FDA-CBER-2022-1614-5939950

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:20', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9ae7b2c-1b28-4f59-bc04-1be2c29ab24d'	System	28 Aug 2020 15:24:34
User entered 'None (0)'	System	28 Aug 2020 15:24:34

FDA-CBER-2022-1614-5939951

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:22', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9ae7b2c-1b28-4f59-bc04-1be2c29ab24d'	System	28 Aug 2020 15:24:34
User entered 'None (0)'	System	28 Aug 2020 15:24:34

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:24', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9ae7b2c-1b28-4f59-bc04-1be2c29ab24d'	System	28 Aug 2020 15:24:34
User entered 'None (0)'	System	28 Aug 2020 15:24:34

FDA-CBER-2022-1614-5939953

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:25', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9ae7b2c-1b28-4f59-bc04-1be2c29ab24d'	System	28 Aug 2020 15:24:34
User entered 'None (0)'	System	28 Aug 2020 15:24:34

FDA-CBER-2022-1614-5939954

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:29', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9ae7b2c-1b28-4f59-bc04-1be2c29ab24d'	System	28 Aug 2020 15:24:34
User entered 'No (N)'	System	28 Aug 2020 15:24:34

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:30', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9ae7b2c-1b28-4f59-bc04-1be2c29ab24d'	System	28 Aug 2020 15:24:34
User entered '28 Aug 2020 11:24'	System	28 Aug 2020 15:24:34

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:01'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939957

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 13:31'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939958

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939959

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:10:09', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '804f15da-ba1c-4238-8f8e-a3b823e8edb6'	System	29 Aug 2020 14:10:29
User entered 'None (0)'	System	29 Aug 2020 14:10:29

FDA-CBER-2022-1614-5939960

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:10:12', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '804f15da-ba1c-4238-8f8e-a3b823e8edb6'	System	29 Aug 2020 14:10:29
User entered 'None (0)'	System	29 Aug 2020 14:10:29

FDA-CBER-2022-1614-5939961

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:10:14', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '804f15da-ba1c-4238-8f8e-a3b823e8edb6'	System	29 Aug 2020 14:10:29
User entered 'None (0)'	System	29 Aug 2020 14:10:29

FDA-CBER-2022-1614-5939962

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:10:16', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '804f15da-ba1c-4238-8f8e-a3b823e8edb6'	System	29 Aug 2020 14:10:29
User entered 'None (0)'	System	29 Aug 2020 14:10:29

FDA-CBER-2022-1614-5939963

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:10:17', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '804f15da-ba1c-4238-8f8e-a3b823e8edb6'	System	29 Aug 2020 14:10:29
User entered 'None (0)'	System	29 Aug 2020 14:10:29

FDA-CBER-2022-1614-5939964

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:10:19', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '804f15da-ba1c-4238-8f8e-a3b823e8edb6'	System	29 Aug 2020 14:10:29
User entered 'None (0)'	System	29 Aug 2020 14:10:29

FDA-CBER-2022-1614-5939965

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:10:23', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '804f15da-ba1c-4238-8f8e-a3b823e8edb6'	System	29 Aug 2020 14:10:29
User entered 'No (N)'	System	29 Aug 2020 14:10:29

FDA-CBER-2022-1614-5939966

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:10:25', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '804f15da-ba1c-4238-8f8e-a3b823e8edb6'	System	29 Aug 2020 14:10:29
User entered '29 Aug 2020 10:10'	System	29 Aug 2020 14:10:29

FDA-CBER-2022-1614-5939967

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '28 Aug 2020 14:26'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939968

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 2'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939970

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939971

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939972

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 3'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939973

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:24:33
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:23', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'a902c62d-abca-4f69-9d9a-bbd5bee84377'	System	30 Aug 2020 21:49:40
User entered 'None (0)'	System	30 Aug 2020 21:49:40

FDA-CBER-2022-1614-5939974

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:24:33
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:24', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'a902c62d-abca-4f69-9d9a-bbd5bee84377'	System	30 Aug 2020 21:49:40
User entered 'None (0)'	System	30 Aug 2020 21:49:40

FDA-CBER-2022-1614-5939975

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:27', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'a902c62d-abca-4f69-9d9a-bbd5bee84377'	System	30 Aug 2020 21:49:40
User entered 'None (0)'	System	30 Aug 2020 21:49:40

FDA-CBER-2022-1614-5939976

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:28', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'a902c62d-abca-4f69-9d9a-bbd5bee84377'	System	30 Aug 2020 21:49:40
User entered 'None (0)'	System	30 Aug 2020 21:49:40

FDA-CBER-2022-1614-5939977

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:29', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'a902c62d-abca-4f69-9d9a-bbd5bee84377'	System	30 Aug 2020 21:49:40
User entered 'None (0)'	System	30 Aug 2020 21:49:40

FDA-CBER-2022-1614-5939978

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:24:33
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:30', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'a902c62d-abca-4f69-9d9a-bbd5bee84377'	System	30 Aug 2020 21:49:40
User entered 'None (0)'	System	30 Aug 2020 21:49:40

FDA-CBER-2022-1614-5939979

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:34', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'a902c62d-abca-4f69-9d9a-bbd5bee84377'	System	30 Aug 2020 21:49:40
User entered 'No (N)'	System	30 Aug 2020 21:49:40

FDA-CBER-2022-1614-5939980

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:24:33
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:36', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'a902c62d-abca-4f69-9d9a-bbd5bee84377'	System	30 Aug 2020 21:49:40
User entered '30 Aug 2020 17:49'	System	30 Aug 2020 21:49:40

FDA-CBER-2022-1614-5939981

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939982

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939983

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 4'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939984

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:24:33
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:37:54', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'cff938c6-a791-4f79-bc43-f2d386f9f75d'	System	31 Aug 2020 22:38:18
User entered 'No interference with activity (1)'	System	31 Aug 2020 22:38:18

FDA-CBER-2022-1614-5939985

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:24:33
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:38:01', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'cff938c6-a791-4f79-bc43-f2d386f9f75d'	System	31 Aug 2020 22:38:18
User entered 'None (0)'	System	31 Aug 2020 22:38:18

FDA-CBER-2022-1614-5939986

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:38:02', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'cff938c6-a791-4f79-bc43-f2d386f9f75d'	System	31 Aug 2020 22:38:18
User entered 'None (0)'	System	31 Aug 2020 22:38:18

FDA-CBER-2022-1614-5939987

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:38:03', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'cff938c6-a791-4f79-bc43-f2d386f9f75d'	System	31 Aug 2020 22:38:18
User entered 'None (0)'	System	31 Aug 2020 22:38:18

FDA-CBER-2022-1614-5939988

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:38:05', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'cff938c6-a791-4f79-bc43-f2d386f9f75d'	System	31 Aug 2020 22:38:18
User entered 'None (0)'	System	31 Aug 2020 22:38:18

FDA-CBER-2022-1614-5939989

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:24:33
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:38:06', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'cff938c6-a791-4f79-bc43-f2d386f9f75d'	System	31 Aug 2020 22:38:18
User entered 'None (0)'	System	31 Aug 2020 22:38:18

FDA-CBER-2022-1614-5939990

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:38:08', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'cff938c6-a791-4f79-bc43-f2d386f9f75d'	System	31 Aug 2020 22:38:18
User entered 'No (N)'	System	31 Aug 2020 22:38:18

FDA-CBER-2022-1614-5939991

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:24:33
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:38:10', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'cff938c6-a791-4f79-bc43-f2d386f9f75d'	System	31 Aug 2020 22:38:18
User entered '31 Aug 2020 18:38'	System	31 Aug 2020 22:38:18

FDA-CBER-2022-1614-5939992

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939993

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939994

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 5'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5939995

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:24:33
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:25', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '6ece0dfa-943e-4603-9ad3-77d8c240505c'	System	01 Sep 2020 22:15:40
User entered 'None (0)'	System	01 Sep 2020 22:15:40

FDA-CBER-2022-1614-5939996

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:24:33
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:28', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '6ece0dfa-943e-4603-9ad3-77d8c240505c'	System	01 Sep 2020 22:15:40
User entered 'None (0)'	System	01 Sep 2020 22:15:40

FDA-CBER-2022-1614-5939997

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:29', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '6ece0dfa-943e-4603-9ad3-77d8c240505c'	System	01 Sep 2020 22:15:40
User entered 'None (0)'	System	01 Sep 2020 22:15:40

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:30', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '6ece0dfa-943e-4603-9ad3-77d8c240505c'	System	01 Sep 2020 22:15:40
User entered 'None (0)'	System	01 Sep 2020 22:15:40

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:31', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '6ece0dfa-943e-4603-9ad3-77d8c240505c'	System	01 Sep 2020 22:15:40
User entered 'None (0)'	System	01 Sep 2020 22:15:40

FDA-CBER-2022-1614-5940000

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:24:33
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:33', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '6ece0dfa-943e-4603-9ad3-77d8c240505c'	System	01 Sep 2020 22:15:40
User entered 'None (0)'	System	01 Sep 2020 22:15:40

FDA-CBER-2022-1614-5940001

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:34', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '6ece0dfa-943e-4603-9ad3-77d8c240505c'	System	01 Sep 2020 22:15:40
User entered 'No (N)'	System	01 Sep 2020 22:15:40

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:24:33
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:36', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '6ece0dfa-943e-4603-9ad3-77d8c240505c'	System	01 Sep 2020 22:15:40
User entered '01 Sep 2020 18:15'	System	01 Sep 2020 22:15:40

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5940004

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5940005

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 6'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5940006

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:24:33
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:07:02', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '1bceef0d-5c6d-4503-bb91-569403eeaa9d'	System	02 Sep 2020 22:07:16
User entered 'None (0)'	System	02 Sep 2020 22:07:16

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:24:33
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:07:03', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '1bceef0d-5c6d-4503-bb91-569403eeaa9d'	System	02 Sep 2020 22:07:16
User entered 'None (0)'	System	02 Sep 2020 22:07:16

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:07:05', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '1bceef0d-5c6d-4503-bb91-569403eeaa9d'	System	02 Sep 2020 22:07:16
User entered 'None (0)'	System	02 Sep 2020 22:07:16

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:07:06', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '1bceef0d-5c6d-4503-bb91-569403eeaa9d'	System	02 Sep 2020 22:07:16
User entered 'None (0)'	System	02 Sep 2020 22:07:16

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:07:07', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '1bceef0d-5c6d-4503-bb91-569403eeaa9d'	System	02 Sep 2020 22:07:16
User entered 'None (0)'	System	02 Sep 2020 22:07:16

FDA-CBER-2022-1614-5940011

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:24:33
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:07:08', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '1bceef0d-5c6d-4503-bb91-569403eeaa9d'	System	02 Sep 2020 22:07:16
User entered 'None (0)'	System	02 Sep 2020 22:07:16

FDA-CBER-2022-1614-5940012

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:07:11', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '1bceef0d-5c6d-4503-bb91-569403eeaa9d'	System	02 Sep 2020 22:07:16
User entered 'No (N)'	System	02 Sep 2020 22:07:16

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:24:33
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:07:13', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '1bceef0d-5c6d-4503-bb91-569403eeaa9d'	System	02 Sep 2020 22:07:16
User entered '02 Sep 2020 18:07'	System	02 Sep 2020 22:07:16

FDA-CBER-2022-1614-5940014

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5940015

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5940016

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 7'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5940017

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:24:33
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:03', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '7440fb8f-cb59-4ea6-82e6-7f96d77ddb78'	System	03 Sep 2020 21:11:17
User entered 'None (0)'	System	03 Sep 2020 21:11:17

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:24:33
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:05', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '7440fb8f-cb59-4ea6-82e6-7f96d77ddb78'	System	03 Sep 2020 21:11:17
User entered 'None (0)'	System	03 Sep 2020 21:11:17

FDA-CBER-2022-1614-5940019

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:06', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '7440fb8f-cb59-4ea6-82e6-7f96d77ddb78'	System	03 Sep 2020 21:11:17
User entered 'None (0)'	System	03 Sep 2020 21:11:17

FDA-CBER-2022-1614-5940020

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:09', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '7440fb8f-cb59-4ea6-82e6-7f96d77ddb78'	System	03 Sep 2020 21:11:17
User entered 'None (0)'	System	03 Sep 2020 21:11:17

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:10', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '7440fb8f-cb59-4ea6-82e6-7f96d77ddb78'	System	03 Sep 2020 21:11:17
User entered 'None (0)'	System	03 Sep 2020 21:11:17

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:24:33
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:11', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '7440fb8f-cb59-4ea6-82e6-7f96d77ddb78'	System	03 Sep 2020 21:11:17
User entered 'None (0)'	System	03 Sep 2020 21:11:17

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:24:33
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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:14', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '7440fb8f-cb59-4ea6-82e6-7f96d77ddb78'	System	03 Sep 2020 21:11:17
User entered 'No (N)'	System	03 Sep 2020 21:11:17

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:24:33
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:15', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '7440fb8f-cb59-4ea6-82e6-7f96d77ddb78'	System	03 Sep 2020 21:11:17
User entered '03 Sep 2020 17:11'	System	03 Sep 2020 21:11:17

FDA-CBER-2022-1614-5940025

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:24:33
PC Open Date & Time

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5940026

US3432334
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:24:33
PC Close Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5940027

US3432334
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Was Contact Attempted?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:36
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	04 Sep 2020 23:36:41

FDA-CBER-2022-1614-5940028

US3432334
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:36
User entered '4 Sep 2020'	Phoebe Cunningham (b) (4)	04 Sep 2020 23:36:41

FDA-CBER-2022-1614-5940029

US3432334
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:36
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	04 Sep 2020 23:36:41

FDA-CBER-2022-1614-5940030

US3432334
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:36
User entered empty.	Phoebe Cunningham (b) (4)	04 Sep 2020 23:36:41

FDA-CBER-2022-1614-5940031

US3432334
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:00:42

FDA-CBER-2022-1614-5940032

US3432334
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:00:42

FDA-CBER-2022-1614-5940033

US3432334
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Was Contact Attempted?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:01:51

FDA-CBER-2022-1614-5940034

US3432334
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:42
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 17:01:51

FDA-CBER-2022-1614-5940035

US3432334
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Sep 2020 17:01:51

FDA-CBER-2022-1614-5940036

US3432334
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:42
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:01:51

FDA-CBER-2022-1614-5940037

US3432334
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:01:56

FDA-CBER-2022-1614-5940038

US3432334
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:01:56

FDA-CBER-2022-1614-5940039

US3432334
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Was Contact Attempted?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	21 Sep 2020 16:07:58

FDA-CBER-2022-1614-5940040

US3432334
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:49
User entered '18 Sep 2020'	Phoebe Cunningham (b) (4)	21 Sep 2020 16:07:58

FDA-CBER-2022-1614-5940041

US3432334
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:49
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	21 Sep 2020 16:07:58

FDA-CBER-2022-1614-5940042

US3432334
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:49
User entered empty.	Phoebe Cunningham (b) (4)	21 Sep 2020 16:07:58

FDA-CBER-2022-1614-5940043

US3432334
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:25
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:05:08

FDA-CBER-2022-1614-5940044

US3432334
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 00:05:08

FDA-CBER-2022-1614-5940045

US3432334
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:24:33
Was this visit performed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:09
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:07:32

FDA-CBER-2022-1614-5940046

US3432334
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:24:33
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:09
User entered '28 Sep 2020'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:07:32

FDA-CBER-2022-1614-5940047

US3432334
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:24:33
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:09
User entered 'Clinic (Clinic)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:07:32

FDA-CBER-2022-1614-5940048

US3432334
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:24:33
Folder OID

Audit	User	Time (GMT)
User entered 'VISIT2'	System	29 Sep 2020 00:07:32

FDA-CBER-2022-1614-5940049

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940050

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Were vital signs assessed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940051

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered '28 Sep 2020'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940052

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered '14:28'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '28 Sep 2020 14:28'	System	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940054

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered '97.7' F	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940055

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Route of measurement

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered 'Other (Other)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940056

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
If Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered 'infrared'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940057

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Pulse *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered '60'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940058

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940059

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered '12'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940060

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940061

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered '120'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940062

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940063

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered '66'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940064

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:24:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940065

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940066

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Were vital signs assessed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered 'No (N)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940067

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940068

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940069

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940070

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940071

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Route of measurement

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940072

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
If Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940073

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Pulse *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940074

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Pulse units

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940075

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940076

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Respiratory Rate units

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940077

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940078

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940079

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940080

US3432334
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:24:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 00:08:23

FDA-CBER-2022-1614-5940081

US3432334
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 09:24:33
Was the physical examination performed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:54
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:39

FDA-CBER-2022-1614-5940082

US3432334
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 09:24:33
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:54
User entered '28 Sep 2020'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:39

FDA-CBER-2022-1614-5940083

US3432334
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:24:33
Was study treatment given?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:02:48
User entered 'No (N)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:24

FDA-CBER-2022-1614-5940084

US3432334
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:24:33
If No, reason not given

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:02:48
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:24

FDA-CBER-2022-1614-5940085

US3432334
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:24:33
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:02:48
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:24

FDA-CBER-2022-1614-5940086

US3432334
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:24:33
What was the study treatment?

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 00:09:24

FDA-CBER-2022-1614-5940087

US3432334
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:24:33
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:02:48
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:24

FDA-CBER-2022-1614-5940088

US3432334
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:24:33
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:02:48
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:24

FDA-CBER-2022-1614-5940089

US3432334
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:24:33
Treatment Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 00:09:24

FDA-CBER-2022-1614-5940090

US3432334
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:24:33
Which arm was used to give treatment?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:02:48
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:24

FDA-CBER-2022-1614-5940091

US3432334
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:24:33
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:02:48
User entered empty.	System	29 Sep 2020 00:09:24

FDA-CBER-2022-1614-5940092

US3432334
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:24:33
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 00:09:24

FDA-CBER-2022-1614-5940093

US3432334
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:24:33
Was the sample collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:04
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:42

FDA-CBER-2022-1614-5940094

US3432334
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:24:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:04
User entered '28 Sep 2020'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:42

FDA-CBER-2022-1614-5940095

US3432334
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:24:33
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:04
User entered '14:40'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:42

FDA-CBER-2022-1614-5940096

US3432334
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:24:33
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '28 Sep 2020 14:40'	System	29 Sep 2020 00:09:42

FDA-CBER-2022-1614-5940097

US3432334
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 26 Nov 2020 09:24:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:10
User closed query 'Samples were not collected, however Collection Date is provided. Please correct.' (Site from System).	System	29 Sep 2020 00:10:18
Query 'Samples were not collected, however Collection Date is provided. Please correct.' answered by data change (Site from System).	System	29 Sep 2020 00:10:18
User entered empty; reason for change Data Entry Error	Natalie Izaguirre (b) (4)	29 Sep 2020 00:10:18
User opened query 'Samples were not collected, however Collection Date is provided. Please correct.' (Site from System).	System	29 Sep 2020 00:09:58
User entered '28 Sep 2020'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:58

FDA-CBER-2022-1614-5940098

US3432334
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:24:33
Lab Test

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:58

FDA-CBER-2022-1614-5940099

US3432334
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:24:33
Was the sample collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:10
User entered 'No (N)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:58

FDA-CBER-2022-1614-5940100

US3432334
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:24:33
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:10
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:58

FDA-CBER-2022-1614-5940101

US3432334
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:24:33
Collection date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 00:09:58

FDA-CBER-2022-1614-5940102

US3432334
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:24:33
Lab Test

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:58

FDA-CBER-2022-1614-5940103

US3432334
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:24:33
Was the sample collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:10
User entered 'No (N)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:58

FDA-CBER-2022-1614-5940104

US3432334
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:24:33
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:10
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:58

FDA-CBER-2022-1614-5940105

US3432334
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:24:33
Collection date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 00:09:58

FDA-CBER-2022-1614-5940106

US3432334
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:13
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:10:27

FDA-CBER-2022-1614-5940107

US3432334
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 00:10:27

FDA-CBER-2022-1614-5940108

US3432334
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Was Contact Attempted?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 16:43:42

FDA-CBER-2022-1614-5940109

US3432334
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:29
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 16:43:42

FDA-CBER-2022-1614-5940110

US3432334
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 16:43:42

FDA-CBER-2022-1614-5940111

US3432334
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:29
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 16:43:42

FDA-CBER-2022-1614-5940112

US3432334
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:31
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Oct 2020 16:23:57

FDA-CBER-2022-1614-5940113

US3432334
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 16:23:57

FDA-CBER-2022-1614-5940114

US3432334
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Was Contact Attempted?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:34
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	12 Oct 2020 18:54:32

FDA-CBER-2022-1614-5940115

US3432334
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:34
User entered '12 Oct 2020'	Xhoi Mitre (b) (4) (b) (4)	12 Oct 2020 18:54:32

FDA-CBER-2022-1614-5940116

US3432334
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:34
User entered 'Contact Made (CONTACT MADE)'	Xhoi Mitre (b) (4) (b) (4)	12 Oct 2020 18:54:32

FDA-CBER-2022-1614-5940117

US3432334
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:34
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	12 Oct 2020 18:54:32

FDA-CBER-2022-1614-5940118

US3432334
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:36
User entered 'Yes (Y)'	Kathleen Garvey (b) (4) (b) (4)	19 Oct 2020 15:12:47

FDA-CBER-2022-1614-5940119

US3432334
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 15:12:47

FDA-CBER-2022-1614-5940120

US3432334
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Was Contact Attempted?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:20:38

FDA-CBER-2022-1614-5940121

US3432334
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:40
User entered '19 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 16:20:38

FDA-CBER-2022-1614-5940122

US3432334
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Oct 2020 16:20:38

FDA-CBER-2022-1614-5940123

US3432334
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:40
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:20:38

FDA-CBER-2022-1614-5940124

US3432334
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:21:29

FDA-CBER-2022-1614-5940125

US3432334
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:21:29

FDA-CBER-2022-1614-5940126

US3432334
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:24:33
Was this visit performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 15:45:54

FDA-CBER-2022-1614-5940127

US3432334
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:24:33
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 15:45:54

FDA-CBER-2022-1614-5940128

US3432334
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:24:33
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Oct 2020 15:45:54

FDA-CBER-2022-1614-5940129

US3432334
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:24:33
Folder OID

Audit	User	Time (GMT)
User entered 'VISIT3'	System	28 Oct 2020 15:45:54

FDA-CBER-2022-1614-5940130

US3432334
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 15:55:15

FDA-CBER-2022-1614-5940131

US3432334
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '28 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 15:55:15

FDA-CBER-2022-1614-5940132

US3432334
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '11:25'	(b) (4), (b) (6)	28 Oct 2020 15:55:15

FDA-CBER-2022-1614-5940133

US3432334
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:25'	System	28 Oct 2020 15:55:15

FDA-CBER-2022-1614-5940134

US3432334
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User entered '97.3' F	(b) (4), (b) (6)	28 Oct 2020 15:55:15

FDA-CBER-2022-1614-5940135

US3432334
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Route of measurement

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	28 Oct 2020 15:55:15

FDA-CBER-2022-1614-5940136

US3432334
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
If Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 15:55:15

FDA-CBER-2022-1614-5940137

US3432334
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Pulse *(xxx)*

Audit	User	Time (GMT)
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Oct 2020 15:55:44
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	28 Oct 2020 15:55:44
User entered '65' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 15:55:44
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Oct 2020 15:55:15
User entered '16'	(b) (4), (b) (6)	28 Oct 2020 15:55:15

FDA-CBER-2022-1614-5940138

US3432334
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Oct 2020 15:55:15

FDA-CBER-2022-1614-5940139

US3432334
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	28 Oct 2020 15:55:15

FDA-CBER-2022-1614-5940140

US3432334
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Oct 2020 15:55:15

FDA-CBER-2022-1614-5940141

US3432334
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '121'	(b) (4), (b) (6)	28 Oct 2020 15:55:15

FDA-CBER-2022-1614-5940142

US3432334
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Oct 2020 15:55:15

FDA-CBER-2022-1614-5940143

US3432334
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '75'	(b) (4), (b) (6)	28 Oct 2020 15:55:15

FDA-CBER-2022-1614-5940144

US3432334
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:24:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Oct 2020 15:55:15

FDA-CBER-2022-1614-5940145

US3432334
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 09:24:33
Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 15:55:52

FDA-CBER-2022-1614-5940146

US3432334
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 09:24:33
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 15:55:52

FDA-CBER-2022-1614-5940147

US3432334
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:24:33
Was the sample collected?

Audit	User	Time (GMT)
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 28Oct2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail.' answered with 'PPD reports receiving this.' (Site from DM).	Jun Bai Park Chang (b) (4)	10 Nov 2020 16:30:03
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 28Oct2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 19:02:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 15:56:27

FDA-CBER-2022-1614-5940148

US3432334
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:24:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '28 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 15:56:27

FDA-CBER-2022-1614-5940149

US3432334
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:24:33
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '11:32'	(b) (4), (b) (6)	28 Oct 2020 15:56:27

FDA-CBER-2022-1614-5940150

US3432334
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:24:33
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:32'	System	28 Oct 2020 15:56:27

FDA-CBER-2022-1614-5940151

US3432334
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 15:56:34

FDA-CBER-2022-1614-5940152

US3432334
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 15:56:34

FDA-CBER-2022-1614-5940153

US3432334
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 64'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5940154

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:33

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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-10-31T12:36:31', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'e9ab420c-5b59-4cc7-a879-96b6e705fe9f'	System	31 Oct 2020 16:37:04
User entered 'No (N)'	System	31 Oct 2020 16:37:04

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:33

Have you been exposed to someone with 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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-10-31T12:36:50', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'e9ab420c-5b59-4cc7-a879-96b6e705fe9f'	System	31 Oct 2020 16:37:04
User entered 'Yes (Y)'	System	31 Oct 2020 16:37:04

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-10-31T12:36:52', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'e9ab420c-5b59-4cc7-a879-96b6e705fe9f'	System	31 Oct 2020 16:37:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Oct 2020 16:37:04

US3432334
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-10-31T12:36:56', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'e9ab420c-5b59-4cc7-a879-96b6e705fe9f'	System	31 Oct 2020 16:37:04
User entered '31 Oct 2020 12:36:56'	System	31 Oct 2020 16:37:04

FDA-CBER-2022-1614-5940158

US3432334
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5940159

US3432334
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5940160

US3432334
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 71'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5940161

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:33

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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-06T12:00:50', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '2b8a3086-efe5-438f-9c3b-183c8bc2b258'	System	08 Nov 2020 20:30:36
User entered 'No (N)'	System	08 Nov 2020 20:30:36

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:33

Have you been exposed to someone with 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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-06T12:00:53', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '2b8a3086-efe5-438f-9c3b-183c8bc2b258'	System	08 Nov 2020 20:30:36
User entered 'No (N)'	System	08 Nov 2020 20:30:36

US3432334
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-06T12:00:56', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '2b8a3086-efe5-438f-9c3b-183c8bc2b258'	System	08 Nov 2020 20:30:36
User entered '06 Nov 2020 12:00:56'	System	08 Nov 2020 20:30:36

FDA-CBER-2022-1614-5940164

US3432334
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 15:13:20

US3432334
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 15:13:20

FDA-CBER-2022-1614-5940166

US3432334
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 78'	System	28 Aug 2020 15:13:20

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:33

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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-11T05:44:47', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'bdbdc9b2-d2d1-4956-b2fc-c2d013b3bf53'	System	11 Nov 2020 10:44:53
User entered 'No (N)'	System	11 Nov 2020 10:44:53

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:33

Have you been exposed to someone with 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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-11T05:44:49', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'bdbdc9b2-d2d1-4956-b2fc-c2d013b3bf53'	System	11 Nov 2020 10:44:53
User entered 'No (N)'	System	11 Nov 2020 10:44:53

US3432334
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-11T05:44:51', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'bdbdc9b2-d2d1-4956-b2fc-c2d013b3bf53'	System	11 Nov 2020 10:44:53
User entered '11 Nov 2020 05:44:51'	System	11 Nov 2020 10:44:53

US3432334
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 15:13:20

US3432334
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 15:13:20
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 15:13:20

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940173

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '25 Oct 2020 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940174

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '29 Oct 2020 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940175

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940176

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '01 Nov 2020 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940177

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '05 Nov 2020 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940178

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940179

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '08 Nov 2020 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940180

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '12 Nov 2020 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940181

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940182

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940183

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940184

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940185

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:33

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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-22T14:45:20', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '54a83663-b0cf-4bbc-867a-b515f2165252'	System	22 Nov 2020 19:45:39
User entered 'No (N)'	System	22 Nov 2020 19:45:39

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:33

Have you been exposed to someone with 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 (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-22T14:45:33', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '54a83663-b0cf-4bbc-867a-b515f2165252'	System	22 Nov 2020 19:45:39
User entered 'No (N)'	System	22 Nov 2020 19:45:39

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-22T14:45:36', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '54a83663-b0cf-4bbc-867a-b515f2165252'	System	22 Nov 2020 19:45:39
User entered '22 Nov 2020 14:45:36'	System	22 Nov 2020 19:45:39

FDA-CBER-2022-1614-5940188

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940189

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940190

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940191

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940192

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940193

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940194

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940195

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940196

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940197

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940198

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940199

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940200

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940201

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940202

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:39:09

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940204

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 19:39:09

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940206

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940207

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940208

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940209

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940210

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940211

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940212

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940213

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940214

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:39:09

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940216

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940217

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940218

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940219

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940220

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940221

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940222

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940223

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940224

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940225

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940226

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940227

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940228

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940229

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940230

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940231

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940232

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940233

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940234

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940235

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940236

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940237

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940238

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:39:09

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940240

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940241

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940242

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940243

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940244

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:39:09

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940246

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940247

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940248

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940249

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940250

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940251

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940252

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 19:39:09

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:39:09

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940255

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940256

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940257

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940258

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940259

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940260

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940261

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940262

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940263

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940264

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940265

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940266

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940267

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940268

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940269

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940270

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940271

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940272

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940273

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940274

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940275

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940276

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940277

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940278

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940279

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940280

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940281

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940282

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940283

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940284

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 19:39:09

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940286

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940287

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940288

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940289

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940290

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940291

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940292

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:39:09

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940294

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940295

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940296

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940297

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940298

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940299

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940300

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940301

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:39:09

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940303

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940304

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940305

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940306

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940307

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940308

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940309

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940310

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940311

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940312

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940313

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940314

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940315

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940316

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940317

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940318

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940319

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940320

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940321

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940322

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940323

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940324

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940325

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940326

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940327

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940328

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940329

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940330

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940331

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940332

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940333

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940334

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940335

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940336

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940337

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940338

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940339

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940340

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940341

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940342

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940343

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940344

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940345

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940346

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940347

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940348

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940349

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940350

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940351

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940352

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940353

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940354

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940355

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940356

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940357

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940358

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:39:09

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940360

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940361

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940362

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940363

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940364

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940365

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940366

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940367

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940368

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940369

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940370

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940371

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940372

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940373

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940374

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940375

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940376

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940377

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940378

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940379

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940380

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940381

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940382

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940383

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940384

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940385

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940386

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940387

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940388

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940389

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940390

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940391

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940392

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940393

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940394

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940395

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940396

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940397

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940398

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940399

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940400

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940401

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940402

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940403

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940404

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940405

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940406

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940407

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940408

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940409

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940410

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940411

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940412

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940413

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940414

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940415

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940416

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940417

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940418

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940419

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940420

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940421

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940422

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940423

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940424

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940425

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940426

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940427

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940428

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940429

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940430

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940431

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940432

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940433

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940434

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940435

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940436

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940437

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940438

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940439

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940440

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940441

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940442

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940443

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940444

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940445

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940446

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940447

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940448

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940449

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940450

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940451

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940452

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940453

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940454

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940455

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940456

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940457

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940458

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940459

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940460

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940461

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940462

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940463

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940464

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940465

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940466

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940467

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940468

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940469

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940470

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940471

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940472

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940473

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940474

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940475

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940476

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940477

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940478

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940479

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940480

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940481

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940482

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940483

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940484

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940485

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940486

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940487

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940488

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '23 Oct 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940489

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '27 Oct 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940490

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940491

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '30 Oct 2022 00:01'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940492

US3432334
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '03 Nov 2022 23:59'	System	19 Nov 2020 19:39:09

FDA-CBER-2022-1614-5940493

US3432334
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Was Contact Attempted?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kathleen Garvey (b) (4) (b) (4)	23 Nov 2020 17:34:33

FDA-CBER-2022-1614-5940494

US3432334
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Kathleen Garvey (b) (4) (b) (4)	23 Nov 2020 17:34:33

FDA-CBER-2022-1614-5940495

US3432334
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4) (b) (4)	23 Nov 2020 17:34:33

FDA-CBER-2022-1614-5940496

US3432334
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:24:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kathleen Garvey (b) (4) (b) (4)	23 Nov 2020 17:34:33

FDA-CBER-2022-1614-5940497

US3432334
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kathleen Garvey (b) (4) (b) (4)	23 Nov 2020 17:35:08

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US3432334
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:24:33
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 17:35:08

FDA-CBER-2022-1614-5940499

US3432334
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 26 Nov 2020 09:24:33
Did the participant experience any adverse events?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:38
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:27:45

FDA-CBER-2022-1614-5940500

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Adverse event

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Asymptomatic COVID-19, LLT: Asymptomatic SARS-CoV-2 infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:37:08
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:37:08
Data point term sent to Coder	System	23 Nov 2020 15:08:53
Query 'For consistency, please update to Covid 19 Infection.' canceled (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:08:51
User opened query 'For consistency, please update to Covid 19 Infection.' (Site from System).	Coder Import (b) (4) (b) (4)	07 Nov 2020 19:36:26
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Asymptomatic COVID-19, LLT: Asymptomatic SARS-CoV-2 infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 06:22:47
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 06:22:47
Data point term sent to Coder	System	18 Sep 2020 19:31:28
User entered 'SARS-CoV-2 Infection (Asymptomatic)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940501

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940502

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940503

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940504

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '16 Sep 2020'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940505

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered empty.	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940506

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940507

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered 'No (N)' reason for change: Data Entry Error	Natalie Izaguirre (b) (4)	29 Sep 2020 00:06:41
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940508

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '26 Sep 2020' reason for change: Data Entry Error	Natalie Izaguirre (b) (4)	29 Sep 2020 00:06:41
User entered empty.	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940509

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered empty.	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940510

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940511

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered 'Grade 1/Mild (Grade 1/Mild)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940512

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940513

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '0'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940514

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '0'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940515

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '0'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940516

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered empty.	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940517

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered empty.	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940518

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered empty.	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940519

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered empty.	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940520

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '0'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940521

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '0'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940522

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '0'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940523

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:26:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 13:12:03
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	18 Sep 2020 19:31:41
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:41
Query 'Data is required. Please complete.' answered with 'updated' (Site from System).	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:35
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 19:31:29
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	18 Sep 2020 19:31:29
User entered empty; reason for change Data Entry Error	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:29
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	18 Sep 2020 19:31:19
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	18 Sep 2020 19:31:19
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:19
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	18 Sep 2020 19:31:10
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940524

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940525

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Action taken with investigational product

Audit	User	Time (GMT)
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 withdrawal is AE. Updated' (Site from System).	Julia Klopfer (b) (4) (b) (4)	24 Nov 2020 23:20:12
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
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	22 Oct 2020 19:20:55
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '1'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940527

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '0'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940528

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '0'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940529

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Natalie Izaguirre (b) (4)	29 Sep 2020 00:06:41
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 19:32:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 19:32:10
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:32:10
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 19:31:10
User entered empty.	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940530

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered empty.	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940531

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered empty.	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940532

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940533

US3432334
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:24:33
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:31:10

FDA-CBER-2022-1614-5940534

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 26 Nov 2020 09:24:33
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:58
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:53:18

FDA-CBER-2022-1614-5940535

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:24:33
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:54:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:54:39
Data point term sent to Coder	System	28 Aug 2020 15:54:24
User entered 'Albuterol'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:54:12

FDA-CBER-2022-1614-5940536

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:24:33
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:54:12

FDA-CBER-2022-1614-5940537

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:24:33
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'Asthma'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:54:12

FDA-CBER-2022-1614-5940538

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:24:33
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered '2'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:54:12

FDA-CBER-2022-1614-5940539

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:24:33
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'puff (PUFF)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:54:12

FDA-CBER-2022-1614-5940540

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:24:33
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:54:12

FDA-CBER-2022-1614-5940541

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:24:33
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'as needed (PRN)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:54:12

FDA-CBER-2022-1614-5940542

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:24:33
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:54:12

FDA-CBER-2022-1614-5940543

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:24:33
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:54:12

FDA-CBER-2022-1614-5940544

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:24:33
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:54:12

FDA-CBER-2022-1614-5940545

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:24:33
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'un UNK 2018'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:54:12

FDA-CBER-2022-1614-5940546

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:24:33
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:54:12

FDA-CBER-2022-1614-5940547

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:24:33
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:54:12

FDA-CBER-2022-1614-5940548

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:24:33
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:54:12

FDA-CBER-2022-1614-5940549

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:24:33
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:54:12

FDA-CBER-2022-1614-5940550

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:24:33
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 15:54:12

FDA-CBER-2022-1614-5940551

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:24:33
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 15:54:12

FDA-CBER-2022-1614-5940552

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:24:33
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 15:54:12

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:24:33
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
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)	17 Oct 2020 20:26:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Oct 2020 20:26:30
Data point term sent to Coder	System	17 Oct 2020 20:25:57
User entered 'Flu Vaccine'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:25:01

FDA-CBER-2022-1614-5940554

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:24:33
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:25:01

FDA-CBER-2022-1614-5940555

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:24:33
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'Flu prophylaxis'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:25:01

FDA-CBER-2022-1614-5940556

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:24:33
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered '0.5'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:25:01

FDA-CBER-2022-1614-5940557

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:24:33
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'mL (mL)'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:25:01

FDA-CBER-2022-1614-5940558

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:24:33
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:25:01

FDA-CBER-2022-1614-5940559

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:24:33
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'once (ONCE)'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:25:01

FDA-CBER-2022-1614-5940560

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:24:33
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:25:01

FDA-CBER-2022-1614-5940561

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:24:33
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'Intramuscular (INTRAMUSCULAR)'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:25:01

FDA-CBER-2022-1614-5940562

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:24:33
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:25:01

FDA-CBER-2022-1614-5940563

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:24:33
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered '05 Oct 2020'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:25:01

FDA-CBER-2022-1614-5940564

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:24:33
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:25:01

FDA-CBER-2022-1614-5940565

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:24:33
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:25:01

FDA-CBER-2022-1614-5940566

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:24:33
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered '5 Oct 2020'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:25:01

FDA-CBER-2022-1614-5940567

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:24:33
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:25:01

FDA-CBER-2022-1614-5940568

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:24:33
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	17 Oct 2020 20:25:01

FDA-CBER-2022-1614-5940569

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:24:33
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	17 Oct 2020 20:25:01

FDA-CBER-2022-1614-5940570

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:24:33
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	17 Oct 2020 20:25:01

FDA-CBER-2022-1614-5940571

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:24:33
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: HEPATITIS VACCINES, PRODUCT: HEPATITIS B VACCINE, PRODUCTSYNONYM: HEPATITIS B [HEPATITIS B VACCINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Nov 2020 13:56:25
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Nov 2020 13:56:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: HEPATITIS VACCINES, PRODUCT: HEPATITIS B VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 02:28:32
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 02:28:32
Data point term sent to Coder	System	17 Oct 2020 20:26:57
User entered 'hepatitis B vaccine'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:26:23

FDA-CBER-2022-1614-5940572

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:24:33
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:26:23

FDA-CBER-2022-1614-5940573

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:24:33
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'hepatitis B prophylaxis'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:26:23

FDA-CBER-2022-1614-5940574

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:24:33
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered '1' reason for change: Data Entry Error	Julia Klopfer (b) (4) (b) (4)	19 Oct 2020 23:35:07
User entered 'UNK'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:26:23

FDA-CBER-2022-1614-5940575

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:24:33
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'Other (OTHER)'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:26:23

FDA-CBER-2022-1614-5940576

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:24:33
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'Injection' reason for change: Data Entry Error	Julia Klopfer (b) (4) (b) (4)	19 Oct 2020 23:35:07
User entered 'UNK'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:26:23

FDA-CBER-2022-1614-5940577

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:24:33
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'once (ONCE)'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:26:23

FDA-CBER-2022-1614-5940578

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:24:33
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:26:23

FDA-CBER-2022-1614-5940579

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:24:33
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'Intramuscular (INTRAMUSCULAR)'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:26:23

FDA-CBER-2022-1614-5940580

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:24:33
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:26:23

FDA-CBER-2022-1614-5940581

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:24:33
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered '05 Oct 2020'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:26:23

FDA-CBER-2022-1614-5940582

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:24:33
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:26:23

FDA-CBER-2022-1614-5940583

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:24:33
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:26:23

FDA-CBER-2022-1614-5940584

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:24:33
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered '5 Oct 2020'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:26:23

FDA-CBER-2022-1614-5940585

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:24:33
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:26:23

FDA-CBER-2022-1614-5940586

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:24:33
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	17 Oct 2020 20:26:23

FDA-CBER-2022-1614-5940587

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:24:33
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	17 Oct 2020 20:26:23

FDA-CBER-2022-1614-5940588

US3432334
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:24:33
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	17 Oct 2020 20:26:23

FDA-CBER-2022-1614-5940589

US3432334
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 26 Nov 2020 09:24:33
Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Sep 2020'	Monica Feeley (b) (4) (b) (4)	22 Oct 2020 19:20:55

FDA-CBER-2022-1614-5940590

US3432334
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 26 Nov 2020 09:24:33
Primary reason for dosing discontinuation

Audit	User	Time (GMT)
User entered 'Due to SARS-COV-2 (COVID)'	Monica Feeley (b) (4) (b) (4)	22 Oct 2020 19:20:55

FDA-CBER-2022-1614-5940591

US3432334
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 26 Nov 2020 09:24:33
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	22 Oct 2020 19:20:55

FDA-CBER-2022-1614-5940592