US3422280 (Prod: Vanderbilt University Medical Center)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:40:19

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US3422280
Form: Participant Creation
Data signed: (b) (4) **01 Apr 2021 23:28:57**
Generated On: 11 Aug 2021 22:40:19

Participant ID	US3422280

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-0804366

US3422280
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **19 Feb 2021 20:54:52**
Generated On: 11 Aug 2021 22:40:19

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	15 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-0804367

US3422280
Folder: Screening
Form: Demographics
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

Date of Birth (MMM yyyy)	(b) (6) 1983
Age	37
Age Units	YEARS
Age (Derived)	37
Sex	Female ■ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ■ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	False
Asian	True
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

FDA-CBER-2022-1614-0804368

US3422280
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

Date of Informed Consent *(dd MMM yyyy)*	15 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐ Amendment 2 ☐ Amendment 3 ■ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ■ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ■
If Yes, previous participant number	
Enrollment Trigger	1

FDA-CBER-2022-1614-0804369

US3422280
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

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

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US3422280
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-0804371

US3422280
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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US3422280
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804373

US3422280
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **19 Feb 2021 20:54:52**
Generated On: 11 Aug 2021 22:40:19

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	15 SEP 2020
Time of assessment *(00:00-23:59)*	10:03 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 10:03
Height *(xxx.x)*	64 in
Weight *(xxx.x)*	123 lb
BMI *(xxx.x)*	21.15705 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0804374

US3422280
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	15 SEP 2020

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

FDA-CBER-2022-1614-0804375

US3422280
Folder: Screening
Form: Childbearing Potential
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

Date of assessment *(dd MMM yyyy)*	15 SEP 2020
Is the participant of childbearing potential?	Yes ■ No ☐
If No, what is the reason?	Surgically sterile ☐ Post-menopausal ☐ Partner medically sterile ☐ Not reached age of Menarche ☐ Other ☐
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	False

FDA-CBER-2022-1614-0804376

US3422280
Folder: Screening
Form: Pregnancy Test
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

Was the pregnancy test performed?	Yes ■ No ☐
Date of test *(dd MMM yyyy)*	15 SEP 2020
Test performed	Urine ■ Serum ☐
Result	Positive ☐ Negative ■
Was FSH sample collected?	Yes ☐ No ■
Collection date	
Collection time	
Collection date and time (derived)	

US3422280
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

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

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

US3422280
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **19 Feb 2021 20:54:52**
Generated On: 11 Aug 2021 22:40:19

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	15 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT1

FDA-CBER-2022-1614-0804380

US3422280
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **19 Feb 2021 20:54:52**
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What was the date of randomization? *(dd MMM yyyy)*	15 SEP 2020
What was the participant's randomization number?	113877
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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US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **19 Feb 2021 20:54:52**
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Height	ND - Not Done
Weight	ND - Not Done

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US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **19 Feb 2021 20:54:52**
Generated On: 11 Aug 2021 22:40:19

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)*	15 SEP 2020
Time of assessment *(00:00-23:59)*	10:03 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 10:03
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	77 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	79 mmHg
Diastolic Blood Pressure units	MMHG

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US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **19 Feb 2021 20:54:52**
Generated On: 11 Aug 2021 22:40:19

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)*	15 SEP 2020
Time of assessment *(00:00-23:59)*	11:11 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 11:11
Temperature *(xxx.x)*	98.8 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	72 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG

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US3422280
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **19 Feb 2021 20:54:52**
Generated On: 11 Aug 2021 22:40:19

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-2022-1614-0804385

US3422280
Folder: Visit 1 Day 1
Form: Pregnancy Test
Data signed: (b) (4) **19 Feb 2021 20:54:52**
Generated On: 11 Aug 2021 22:40:19

Was the pregnancy test performed?	Yes ☐ No ■
Date of test *(dd MMM yyyy)*	
Test performed	Urine ☐ Serum ☐
Result	Positive ☐ Negative ☐
Was FSH sample collected?	Yes ☐ No ■
Collection date	
Collection time	
Collection date and time (derived)	

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US3422280
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **19 Feb 2021 20:54:52**
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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)*	15 SEP 2020
What was the treatment time? *(00:00-23:59)*	10:41 (24 HR)
Treatment Date and Time (derived)	15 SEP 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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US3422280
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **19 Feb 2021 20:54:52**
Generated On: 11 Aug 2021 22:40:19

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	15 SEP 2020
Collection time *(00:00-23:59)*	10:15 (24 HR)
Collection date and time (derived)	15 SEP 2020 10:15

US3422280
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **19 Feb 2021 20:54:52**
Generated On: 11 Aug 2021 22:40:19

Collection date *(dd MMM yyyy)*			15 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:09	15 SEP 2020 10:09
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0804389

US3422280
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **19 Feb 2021 20:54:52**
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804390

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:40:19

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**	98.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	15 SEP 2020 11:14
PC Open Date & Time	15 SEP 2020 11:01
PC Close Date & Time	15 SEP 2020 13:31

FDA-CBER-2022-1614-0804391

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.0 °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	15 SEP 2020 19:29
PC Open Date & Time	15 SEP 2020 14:26
PC Close Date & Time	16 SEP 2020 11:59

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US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	16 SEP 2020 20:08
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:40:19

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**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	17 SEP 2020 20:03
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

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US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.9 °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	18 SEP 2020 20:02
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

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Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	19 SEP 2020 20:03
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

FDA-CBER-2022-1614-0804396

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	20 SEP 2020 20:07
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	21 SEP 2020 20:02
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:40:19

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	15 SEP 2020 11:15
PC Open Date & Time	15 SEP 2020 11:01
PC Close Date & Time	15 SEP 2020 13:31

FDA-CBER-2022-1614-0804399

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:40:19

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	15 SEP 2020 19:28
PC Open Date & Time	15 SEP 2020 14:26
PC Close Date & Time	16 SEP 2020 11:59

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	16 SEP 2020 20:09
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

FDA-CBER-2022-1614-0804401

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:40:19

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	17 SEP 2020 20:03
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:40:19

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	18 SEP 2020 20:01
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:40:19

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	19 SEP 2020 20:03
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	20 SEP 2020 20:07
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:40:19

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	21 SEP 2020 20:02
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐

FDA-CBER-2022-1614-0804407

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804408

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19

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-2022-1614-0804409

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☑ Yes ☐
PC Time stamp	15 SEP 2020 19:29
PC Open Date & Time	15 SEP 2020 14:26
PC Close Date & Time	16 SEP 2020 11:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19

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-2022-1614-0804411

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19

	Yes ☐
PC Time stamp	16 SEP 2020 20:10
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

FDA-CBER-2022-1614-0804412

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19

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-2022-1614-0804413

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19

	Yes ☐
PC Time stamp	17 SEP 2020 20:03
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

FDA-CBER-2022-1614-0804414

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19

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-2022-1614-0804415

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19

	Yes ☐
PC Time stamp	18 SEP 2020 20:00
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19

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-2022-1614-0804417

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19

	Yes ☐
PC Time stamp	19 SEP 2020 20:03
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19

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-2022-1614-0804419

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19

	Yes ☐
PC Time stamp	20 SEP 2020 20:07
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19

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-2022-1614-0804421

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19

	Yes ☐
PC Time stamp	21 SEP 2020 20:02
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3422280
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	22 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-2022-1614-0804423

US3422280
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804424

US3422280
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	29 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-2022-1614-0804425

US3422280
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804426

US3422280
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	6 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-2022-1614-0804427

US3422280
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804428

US3422280
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **19 Feb 2021 20:54:53**
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804429

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **19 Feb 2021 20:54:53**
Generated On: 11 Aug 2021 22:40:19

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	16 OCT 2020
Time of assessment *(00:00-23:59)*	8:21 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 8:21
Temperature *(xxx.x)*	98.6 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	72 mmHg
Diastolic Blood Pressure units	MMHG

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **19 Feb 2021 20:54:53**
Generated On: 11 Aug 2021 22:40:19

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	16 OCT 2020
Time of assessment *(00:00-23:59)*	9:25 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 9:25
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0804431

US3422280
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **19 Feb 2021 20:54:53**
Generated On: 11 Aug 2021 22:40:19

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

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

FDA-CBER-2022-1614-0804432

US3422280
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Data signed: (b) (4) **19 Feb 2021 20:54:53**
Generated On: 11 Aug 2021 22:40:19

Was the pregnancy test performed?	Yes ■ No ☐
Date of test *(dd MMM yyyy)*	16 OCT 2020
Test performed	Urine ■ Serum ☐
Result	Positive ☐ Negative ■
Was FSH sample collected?	Yes ☐ No ■
Collection date	
Collection time	
Collection date and time (derived)	

FDA-CBER-2022-1614-0804433

US3422280
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **19 Feb 2021 20:54:52**
Generated On: 11 Aug 2021 22:40:19

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	16 OCT 2020
What was the treatment time? *(00:00-23:59)*	08:50 (24 HR)
Treatment Date and Time (derived)	16 OCT 2020 08:50
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-0804434

US3422280
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **19 Feb 2021 20:54:52**
Generated On: 11 Aug 2021 22:40:19

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	16 OCT 2020
Collection time *(00:00-23:59)*	8:35 (24 HR)
Collection date and time (derived)	16 OCT 2020 8:35

FDA-CBER-2022-1614-0804435

US3422280
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **19 Feb 2021 20:54:52**
Generated On: 11 Aug 2021 22:40:19

Collection date *(dd MMM yyyy)*			16 OCT 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	8:37	16 OCT 2020 8:37
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0804436

US3422280
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **19 Feb 2021 20:54:52**
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804437

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:40:19

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**	98.4 °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	16 OCT 2020 09:20
PC Open Date & Time	16 OCT 2020 09:10
PC Close Date & Time	16 OCT 2020 11:40

FDA-CBER-2022-1614-0804438

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	16 OCT 2020 18:49
PC Open Date & Time	16 OCT 2020 12:35
PC Close Date & Time	17 OCT 2020 11:59

FDA-CBER-2022-1614-0804439

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	99.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	17 OCT 2020 16:52
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

FDA-CBER-2022-1614-0804440

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:40:19

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**	97.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	18 OCT 2020 19:59
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

FDA-CBER-2022-1614-0804441

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	19 OCT 2020 21:07
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

FDA-CBER-2022-1614-0804442

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	20 OCT 2020 19:18
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	21 OCT 2020 20:02
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.4 °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	22 OCT 2020 21:10
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

FDA-CBER-2022-1614-0804445

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	16 OCT 2020 09:21
PC Open Date & Time	16 OCT 2020 09:10
PC Close Date & Time	16 OCT 2020 11:40

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ■
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	16 OCT 2020 18:49
PC Open Date & Time	16 OCT 2020 12:35
PC Close Date & Time	17 OCT 2020 11:59

FDA-CBER-2022-1614-0804447

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:40:19

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.	110
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.	110
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	17 OCT 2020 16:55
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:40:19

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 ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	110
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.	110
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	18 OCT 2020 19:59
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ■ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	90
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	19 OCT 2020 21:07
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:40:19

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 ○
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	900
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ○ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○ Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	20 OCT 2020 19:20
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

FDA-CBER-2022-1614-0804451

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:40:19

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	21 OCT 2020 20:02
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	22 OCT 2020 21:10
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐

FDA-CBER-2022-1614-0804454

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ● Yes ○
PC Time stamp	16 OCT 2020 09:22
PC Open Date & Time	16 OCT 2020 09:10
PC Close Date & Time	16 OCT 2020 11:40

FDA-CBER-2022-1614-0804455

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19

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-2022-1614-0804456

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☑ Yes ☐
PC Time stamp	16 OCT 2020 18:50
PC Open Date & Time	16 OCT 2020 12:35
PC Close Date & Time	17 OCT 2020 11:59

FDA-CBER-2022-1614-0804457

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19

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-2022-1614-0804458

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19

	Yes ☐
PC Time stamp	17 OCT 2020 16:53
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

FDA-CBER-2022-1614-0804459

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19

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-2022-1614-0804460

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19

	Yes ☐
PC Time stamp	18 OCT 2020 20:00
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

FDA-CBER-2022-1614-0804461

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19

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-2022-1614-0804462

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19

	Yes ☐
PC Time stamp	19 OCT 2020 21:27
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

FDA-CBER-2022-1614-0804463

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19

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-2022-1614-0804464

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19

	Yes ☐
PC Time stamp	20 OCT 2020 19:19
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

FDA-CBER-2022-1614-0804465

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19

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-2022-1614-0804466

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19

	Yes ☐
PC Time stamp	21 OCT 2020 20:03
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

FDA-CBER-2022-1614-0804467

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19

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-2022-1614-0804468

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19

	Yes ☐
PC Time stamp	22 OCT 2020 21:10
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3422280
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	23 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-2022-1614-0804470

US3422280
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804471

US3422280
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	30 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-2022-1614-0804472

US3422280
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804473

US3422280
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	5 NOV 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-0804474

US3422280
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **19 Feb 2021 20:54:49**
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804475

US3422280
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **19 Feb 2021 20:54:53**
Generated On: 11 Aug 2021 22:40:19

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	16 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT3

FDA-CBER-2022-1614-0804476

US3422280
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **19 Feb 2021 20:54:53**
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **19 Feb 2021 20:54:53**
Generated On: 11 Aug 2021 22:40:19

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.

US3422280
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **19 Feb 2021 20:54:53**
Generated On: 11 Aug 2021 22:40:19

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	16 NOV 2020
Collection time *(00:00-23:59)*	08:10 (24 HR)
Collection date and time (derived)	16 NOV 2020 08:10

US3422280
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **19 Feb 2021 20:54:53**
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804480

US3422280
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 12:00:26
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

FDA-CBER-2022-1614-0804481

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 13:53:54
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 06:28:16
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

FDA-CBER-2022-1614-0804483

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 22:37:47
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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	10 DEC 2020 06:02:15
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

FDA-CBER-2022-1614-0804485

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 05:29:07
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

FDA-CBER-2022-1614-0804486

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 DEC 2020 07:20:29
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

FDA-CBER-2022-1614-0804487

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 DEC 2020 06:51:12
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

FDA-CBER-2022-1614-0804488

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 06:01:53
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

FDA-CBER-2022-1614-0804489

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 JAN 2021 12:33:31
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 JAN 2021 05:41:45
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

FDA-CBER-2022-1614-0804491

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 JAN 2021 05:05:12
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 12:00:33
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

FDA-CBER-2022-1614-0804493

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 05:53:30
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

FDA-CBER-2022-1614-0804494

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 01:24:41
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

FDA-CBER-2022-1614-0804495

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 FEB 2021 18:00:29
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

FDA-CBER-2022-1614-0804496

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 04:53:41
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 MAR 2021 05:21:55
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

FDA-CBER-2022-1614-0804498

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 MAR 2021 21:58:02
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

FDA-CBER-2022-1614-0804499

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 MAR 2021 12:00:33
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 APR 2021 04:11:12
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

FDA-CBER-2022-1614-0804501

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Date and time of submission	09 APR 2021 07:21:49
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

FDA-CBER-2022-1614-0804502

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 APR 2021 07:47:07
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 APR 2021 07:16:00
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Date and time of submission	01 MAY 2021 12:00:25
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

FDA-CBER-2022-1614-0804505

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-2022-1614-0804506

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804511

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0804520

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804521

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0804526

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0804532

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804539

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804541

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804547

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804551

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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-2022-1614-0804554

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0804558

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804559

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804561

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804565

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804571

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804573

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

FDA-CBER-2022-1614-0804574

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

FDA-CBER-2022-1614-0804575

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 523
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0804588

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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-2022-1614-0804594

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804596

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 558
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0804598

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0804604

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0804624

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0804626

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804627

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804635

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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-2022-1614-0804636

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804645

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0804646

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

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

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804655

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804656

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804661

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804663

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 ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804667

US3422280
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 11 Aug 2021 22:40:19

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		04 MAR 2021 04:53:51

US3422280
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:00:01**
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804669

US3422280
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:00:01**
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **01 Apr 2021 23:28:58**
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804671

US3422280
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **01 Apr 2021 23:28:58**
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804672

US3422280
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **01 Apr 2021 23:28:58**
Generated On: 11 Aug 2021 22:40:19

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	12 FEB 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0804673

US3422280
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **01 Apr 2021 23:28:58**
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804674

US3422280
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **01 Apr 2021 23:28:58**
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804675

US3422280
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **01 Apr 2021 23:28:58**
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804676

US3422280
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **01 Apr 2021 23:28:58**
Generated On: 11 Aug 2021 22:40:19

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	31 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT4

FDA-CBER-2022-1614-0804677

US3422280
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **01 Apr 2021 23:28:58**
Generated On: 11 Aug 2021 22:40:19

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

US3422280
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Data signed: (b) (4) **01 Apr 2021 23:28:58**
Generated On: 11 Aug 2021 22:40:19

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.

US3422280
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **01 Apr 2021 23:28:58**
Generated On: 11 Aug 2021 22:40:19

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	31 MAR 2021
Collection time *(00:00-23:59)*	08:25 (24 HR)
Collection date and time (derived)	31 MAR 2021 08:25

US3422280
Folder: Visit 4 Day 209 (1)
Form: Continuing
Data signed: (b) (4) **01 Apr 2021 23:28:58**
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804681

US3422280
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19

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

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

US3422280
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:40:19

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

FDA-CBER-2022-1614-0804684

Generate Next COVID-19 Assessment	Yes ☐ No ☐

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **01 Apr 2021 23:28:58**
Generated On: 11 Aug 2021 22:40:19

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	14 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	UNBLND_DECIDE

FDA-CBER-2022-1614-0804686

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **14 Apr 2021 19:27:23**
Generated On: 11 Aug 2021 22:40:19

Date of updated informed consent *(dd MMM yyyy)*	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ■ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ■
Date of unblinding *(dd MMM yyyy)*	14 JAN 2021
Participant randomization assignment	mRNA-1273 ■ Placebo ☐
Actual Dose 1	mRNA-1273 ■ Placebo ☐ Not Administered ☐
Actual Dose 2	mRNA-1273 ■ Placebo ☐ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☐ No ■
Placebo Only Flag	
Continuing with mRNA-1273	

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **01 Apr 2021 23:28:58**
Generated On: 11 Aug 2021 22:40:19

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	14 JAN 2021
Collection time *(00:00-23:59)*	10:59 (24 HR)
Collection date and time (derived)	14 JAN 2021 10:59

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **01 Apr 2021 23:28:58**
Generated On: 11 Aug 2021 22:40:19

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	14 JAN 2021
Collection time *(00:00 - 23:59)*	10:57
Collection Date and Time (derived)	14 JAN 2021 10:57

US3422280
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **01 Apr 2021 23:28:57**
Generated On: 11 Aug 2021 22:40:19

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

If Yes, enter details on the Adverse Events form.

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **01 Apr 2021 23:28:58**
Generated On: 11 Aug 2021 22:40:19

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

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

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **01 Apr 2021 23:28:57**
Generated On: 11 Aug 2021 22:40:19

Name of Medication	NORETHINDRONE AC-ETH ESTRADIOL
Prophylaxis	Yes ■ No ☐
Indication	BIRTH CONTROL
Dose per administration	1/20
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	MG/MCG
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2012
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **01 Apr 2021 23:28:57**
Generated On: 11 Aug 2021 22:40:19

Name of Medication	ALLEGRA
Prophylaxis	Yes ☐ No ■
Indication	ALLERGIC RHINITS
Dose per administration	180
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 ☐

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

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **01 Apr 2021 23:28:57**
Generated On: 11 Aug 2021 22:40:19

Name of Medication	RETIN-A
Prophylaxis	Yes ☐ No ■
Indication	ACNE
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	APPLICATION
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 ☐

FDA-CBER-2022-1614-0804696

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

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ■
Indication	HEADACHE/BODY ACHES/PAIN AT INJECTION SITE
Dose per administration	800
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	19 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 ☐

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **01 Apr 2021 23:28:57**
Generated On: 11 Aug 2021 22:40:19

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ■ No ☐
Indication	HEALTH MAINTENANCE
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 ■
	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)*	13 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	13 NOV 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 ☐

US3422280
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **01 Apr 2021 23:28:58**
Generated On: 11 Aug 2021 22:40:19

Were any concomitant procedures performed?	Yes ☐
	No ■

If yes, please complete Concomitant Procedures form.

US3422280
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 11 Aug 2021 22:40:19

Date of dosing discontinuation (dd MMM yyyy)	
Primary reason for dosing discontinuation	AE (specify) ☐ SAE (specify) ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Due to SARS-COV-2 ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	

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US3422280
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:40:19

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 ☐

Audit

US3422280 (Prod: Vanderbilt University Medical Center)

US3422280
Form: Participant Creation
Generated On: 11 Aug 2021 22:40:19
Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'US3422280'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 14:59:52

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US3422280
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Yes (Y)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:24:21

US3422280
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '15 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 14:59:53

US3422280
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Clinic (Clinic)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:24:21

US3422280
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered 'SCRN'	System	15 Sep 2020 15:24:21

US3422280
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:40:19
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered (b) (6) 1983'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 14:59:54

FDA-CBER-2022-1614-0804711

US3422280
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:40:19
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '37'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:24:41

US3422280
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:40:19
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered 'YEARS'	System	15 Sep 2020 15:24:41

US3422280
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:40:19
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered '37'	System	15 Sep 2020 15:24:56

US3422280
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:40:19
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Female (F)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:24:41

FDA-CBER-2022-1614-0804715

US3422280
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:40:19
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:24:41

US3422280
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:40:19
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '0'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:24:41

US3422280
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:40:19
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '0'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:24:41

US3422280
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:40:19
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '1'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:24:41

US3422280
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:40:19
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '0'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:24:41

US3422280
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:40:19
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '0'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:24:41

US3422280
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:40:19
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '0'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:24:41

US3422280
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:40:19
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered empty.	April Hanlotxomphou (b) (4)	15 Sep 2020 15:24:41

US3422280
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:40:19
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '0'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:24:41

US3422280
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:40:19
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '0'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:24:41

US3422280
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:40:19
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '15 Sep 2020'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:24:56

US3422280
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:40:19
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered 'Sep 2020'	System	15 Sep 2020 15:24:56

US3422280
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:40:19
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered '2020'	System	15 Sep 2020 15:24:56

US3422280
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:40:19
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Amendment 3 (3)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:24:56

US3422280
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:40:19
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:24:56

US3422280
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:40:19
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered empty.	April Hanlotxomphou (b) (4)	15 Sep 2020 15:24:56

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US3422280
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:40:19
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered empty.	April Hanlotxomphou (b) (4)	15 Sep 2020 15:24:56

US3422280
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:40:19
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'No (N)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:24:56

US3422280
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:40:19
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 14:59:53

US3422280
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:40:19
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered '1'	System	15 Sep 2020 15:25:03

US3422280
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 11 Aug 2021 22:40:19
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:03

US3422280
Folder: Screening
Form: Medical History Summary
Generated On: 11 Aug 2021 22:40:19
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:21:36

US3422280
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:40:19
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 18:25:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 18:25:47
Data point term sent to Coder	System	15 Sep 2020 18:24:50
User entered 'Allergic Rhinitis'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:24:07

US3422280
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:40:19
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'un UNK 2012' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 17:56:01
User entered '01 Jun 2012'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:24:07

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US3422280
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:40:19
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:24:07

US3422280
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:40:19
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:24:07

US3422280
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:40:19
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:24:07

US3422280
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:40:19
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:24:07

US3422280
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:40:19
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered 'Jan 2012'	System	16 Oct 2020 17:56:01
User entered 'Jun 2012'	System	15 Sep 2020 18:24:07

US3422280
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:40:19
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered '2012'	System	15 Sep 2020 18:24:07

FDA-CBER-2022-1614-0804745

US3422280
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:40:19
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered empty.	System	15 Sep 2020 18:24:07

US3422280
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:40:19
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered empty.	System	15 Sep 2020 18:24:07

FDA-CBER-2022-1614-0804747

US3422280
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:40:19
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Acnes, PT: Acne, LLT: Acne - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 18:25:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 18:25:47
Data point term sent to Coder	System	15 Sep 2020 18:24:52
User entered 'Acne'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:24:32

US3422280
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:40:19
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'un Jan 2020' reason for change: New Information	(b) (4), (b) (6)	16 Oct 2020 17:56:24
User entered '01 Jan 2020'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:24:32

US3422280
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:40:19
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:24:32

US3422280
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:40:19
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:24:32

FDA-CBER-2022-1614-0804751

US3422280
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:40:19
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:24:32

US3422280
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:40:19
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:24:32

US3422280
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:40:19
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered 'Jan 2020'	System	15 Sep 2020 18:24:32

US3422280
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:40:19
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered '2020'	System	15 Sep 2020 18:24:32

FDA-CBER-2022-1614-0804755

US3422280
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:40:19
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered empty.	System	15 Sep 2020 18:24:32

US3422280
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:40:19
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered empty.	System	15 Sep 2020 18:24:32

US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:26:24

US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '15 Sep 2020'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:26:24

US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '10:03'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:26:24

US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered '15 Sep 2020 10:03'	System	15 Sep 2020 18:26:24

US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '64' in	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:26:24
DataPoint set to visible.	System	15 Sep 2020 15:25:03

US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '123' lb	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:26:24
DataPoint set to visible.	System	15 Sep 2020 15:25:03

US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered '21.15705'	System	15 Sep 2020 18:26:24
DataPoint set to visible.	System	15 Sep 2020 15:25:03

US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered 'kg/m2'	System	15 Sep 2020 18:26:24
DataPoint set to visible.	System	15 Sep 2020 15:25:03

US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 12:54:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 18:28:24
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (b) (4) (b) (4)	22 Sep 2020 17:28:30
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 17:28:25
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	22 Sep 2020 17:28:25
User entered '98.7' F	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:26:24

US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	22 Sep 2020 17:28:25
User entered 'Oral (Oral)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:26:24

US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:26:24

US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 12:54:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 18:28:24
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (b) (4) (b) (4)	22 Sep 2020 17:28:33
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 17:28:25
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	22 Sep 2020 17:28:25
User entered '77'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:26:24

US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered 'bpm'	System	25 Sep 2020 18:28:24
User entered empty.	System	22 Sep 2020 17:28:25
User entered 'bpm'	System	15 Sep 2020 18:26:24

US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 12:55:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 18:28:24
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (b) (4) (b) (4)	22 Sep 2020 17:28:37
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 17:28:25
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	22 Sep 2020 17:28:25
User entered '14'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:26:24

US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered 'breaths/min'	System	25 Sep 2020 18:28:24
User entered empty.	System	22 Sep 2020 17:28:25
User entered 'breaths/min'	System	15 Sep 2020 18:26:24

US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 12:55:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 18:28:24
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (b) (4) (b) (4)	22 Sep 2020 17:28:40
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 17:28:25
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	22 Sep 2020 17:28:25
User entered '121'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:26:24

US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered 'mmHg'	System	25 Sep 2020 18:28:24
User entered empty.	System	22 Sep 2020 17:28:25
User entered 'mmHg'	System	15 Sep 2020 18:26:24

US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 12:55:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 18:28:24
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (b) (4) (b) (4)	22 Sep 2020 17:28:43
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 17:28:25
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	22 Sep 2020 17:28:25
User entered '79'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:26:24

US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered 'mmHg'	System	25 Sep 2020 18:28:24
User entered empty.	System	22 Sep 2020 17:28:25
User entered 'mmHg'	System	15 Sep 2020 18:26:24

US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14

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US3422280
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14

FDA-CBER-2022-1614-0804778

US3422280
Folder: Screening
Form: Physical Examination
Generated On: 11 Aug 2021 22:40:19
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:31:27

US3422280
Folder: Screening
Form: Physical Examination
Generated On: 11 Aug 2021 22:40:19
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '15 Sep 2020'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:31:27

US3422280
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 22:40:19
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '15 Sep 2020'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:32:01

US3422280
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 22:40:19
Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:32:01

US3422280
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 22:40:19
If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:32:01

US3422280
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 22:40:19
If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:32:01

US3422280
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 22:40:19
If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:32:01

US3422280
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 22:40:19
Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:32:01

US3422280
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 22:40:19
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:32:01

US3422280
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 22:40:19
Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:32:01

US3422280
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:33:20

US3422280
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '15 Sep 2020'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:33:20

US3422280
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Urine (URINE)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:33:20

US3422280
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Negative (NEGATIVE)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:33:20

US3422280
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:33:20

US3422280
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:33:20

US3422280
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:33:20

US3422280
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered empty.	System	15 Sep 2020 18:33:20

US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'No (N)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'No (N)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'No (N)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'No (N)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'No (N)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'No (N)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'No (N)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'No (N)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'No (N)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'No (N)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'No (N)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered empty.	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '0'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '0'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '0'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '0'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '0'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '1'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

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US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '0'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

US3422280
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:40:19
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered empty.	April Hanlotxomphou (b) (4)	15 Sep 2020 15:25:42

US3422280
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:34:42

US3422280
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '15 Sep 2020'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:34:42

US3422280
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Clinic (Clinic)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:34:42

US3422280
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'VISIT1'	System	15 Sep 2020 18:34:42

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US3422280
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:40:19
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '15 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 15:21:30

US3422280
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:40:19
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '113877'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 15:21:30

US3422280
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:40:19
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 15:21:30

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US3422280
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:40:19
Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'No (N)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:26:05

US3422280
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:40:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'No (N)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:26:05

US3422280
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:40:19
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'No (N)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:26:05

FDA-CBER-2022-1614-0804827

US3422280
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:40:19
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'No (N)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:26:05

FDA-CBER-2022-1614-0804828

US3422280
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:40:19
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'No (N)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:26:05

FDA-CBER-2022-1614-0804829

US3422280
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:40:19
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	22 Sep 2020 17:28:10
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:15:06
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:15:05

FDA-CBER-2022-1614-0804830

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:40:19
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 18:28:34
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	22 Sep 2020 17:28:04
User entered '64' in	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:40:19
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 18:28:34
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	22 Sep 2020 17:28:04
User entered '123' lb	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:40:19
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 18:28:34
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	22 Sep 2020 17:28:04
User entered '64' in	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:40:19
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 18:28:34
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	22 Sep 2020 17:28:04
User entered '123' lb	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

FDA-CBER-2022-1614-0804834

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User accepted default value 'Pre-Dose (PREDOSE)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '15 Sep 2020'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '10:03'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered '15 Sep 2020 10:03'	System	15 Sep 2020 18:36:03

FDA-CBER-2022-1614-0804839

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '98.7' F	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Oral (Oral)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

FDA-CBER-2022-1614-0804841

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '77'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

FDA-CBER-2022-1614-0804843

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'bpm'	System	15 Sep 2020 18:36:03

FDA-CBER-2022-1614-0804844

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '14'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'breaths/min'	System	15 Sep 2020 18:36:03

FDA-CBER-2022-1614-0804846

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '121'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'mmHg'	System	15 Sep 2020 18:36:03

FDA-CBER-2022-1614-0804848

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '79'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

FDA-CBER-2022-1614-0804849

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'mmHg'	System	15 Sep 2020 18:36:03

FDA-CBER-2022-1614-0804850

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:40:19
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 18:28:34
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	22 Sep 2020 17:28:04
User entered '64' in	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:40:19
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 18:28:34
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	22 Sep 2020 17:28:04
User entered '123' lb	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User accepted default value 'Post-Dose (POSTDOSE)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

FDA-CBER-2022-1614-0804854

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '15 Sep 2020'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '11:11'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered '15 Sep 2020 11:11'	System	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '98.8' F	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Oral (Oral)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

FDA-CBER-2022-1614-0804859

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '72'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

FDA-CBER-2022-1614-0804861

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'bpm'	System	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '16'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

FDA-CBER-2022-1614-0804863

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'breaths/min'	System	15 Sep 2020 18:36:03

FDA-CBER-2022-1614-0804864

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '116'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'mmHg'	System	15 Sep 2020 18:36:03

FDA-CBER-2022-1614-0804866

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '74'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:03

FDA-CBER-2022-1614-0804867

US3422280
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'mmHg'	System	15 Sep 2020 18:36:03

FDA-CBER-2022-1614-0804868

US3422280
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 11 Aug 2021 22:40:19
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:15

US3422280
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 11 Aug 2021 22:40:19
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:15

FDA-CBER-2022-1614-0804870

US3422280
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User closed query 'Per CDM: As a pregnancy test is recorded on Screening page, please update to NO per CCGs pg 15-16, and remove pregnancy test data form this page.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 18:41:45
Query 'Per CDM: As a pregnancy test is recorded on Screening page, please update to NO per CCGs pg 15-16, and remove pregnancy test data form this page.' answered with 'form corrected per query' (Site from DM).	Wendy Winn (b) (4) (b) (4)	29 Sep 2020 17:28:51
User entered 'No (N)' reason for change: Data Entry Error	Wendy Winn (b) (4) (b) (4)	29 Sep 2020 17:28:25
User opened query 'Per CDM: As a pregnancy test is recorded on Screening page, please update to NO per CCGs pg 15-16, and remove pregnancy test data form this page.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:58:03
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:26

US3422280
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Sep 2020 17:28:42
User entered empty; reason for change Data Entry Error	Wendy Winn (b) (4) (b) (4)	29 Sep 2020 17:28:42
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Sep 2020 17:28:25
User entered '1 ' (non-conformant).	Wendy Winn (b) (4) (b) (4)	29 Sep 2020 17:28:25
User entered '15 Sep 2020'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:26

US3422280
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty; reason for change Data Entry Error	Wendy Winn (b) (4) (b) (4)	29 Sep 2020 17:28:25
User entered 'Urine (URINE)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:26

US3422280
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty; reason for change Data Entry Error	Wendy Winn (b) (4) (b) (4)	29 Sep 2020 17:28:25
User entered 'Negative (NEGATIVE)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:26

US3422280
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User closed query 'Per CDM: A yes/no response is required for this field. Please update.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:34:33
Query 'Per CDM: A yes/no response is required for this field. Please update.' answered with 'corrected' (Site from DM).	Cindy Trimmer (b) (4) (b) (4)	12 Oct 2020 20:34:01
User entered 'No (N)' reason for change: Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	12 Oct 2020 20:33:55
User opened query 'Per CDM: A yes/no response is required for this field. Please update.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 18:42:03
User entered empty; reason for change Data Entry Error	Wendy Winn (b) (4) (b) (4)	29 Sep 2020 17:28:25
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:26

US3422280
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:26

US3422280
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:36:26

US3422280
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered empty.	System	15 Sep 2020 18:36:26

FDA-CBER-2022-1614-0804878

US3422280
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:40:19
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Yes (Y)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:43:59

US3422280
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:40:19
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	April Hanlotxomphou (b) (4)	15 Sep 2020 15:43:59

US3422280
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:40:19
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	April Hanlotxomphou (b) (4)	15 Sep 2020 15:43:59

US3422280
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:40:19
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 15:43:59

US3422280
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:40:19
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '15 Sep 2020'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:43:59

US3422280
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:40:19
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '10:41'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:43:59

US3422280
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:40:19
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered '15 Sep 2020 10:41'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0804885

US3422280
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:40:19
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Left Arm (LEFT ARM)'	April Hanlotxomphou (b) (4)	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0804886

US3422280
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:40:19
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'ONCE'	System	15 Sep 2020 15:43:59

US3422280
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:40:19
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 15:43:59

US3422280
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:40:19
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:39:07

US3422280
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:40:19
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '15 Sep 2020'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:39:07

US3422280
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:40:19
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '10:15'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:39:07

US3422280
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:40:19
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered '15 Sep 2020 10:15'	System	15 Sep 2020 18:39:07

US3422280
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 11 Aug 2021 22:40:19
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '15 Sep 2020'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:39:23

US3422280
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:40:19
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:39:23

US3422280
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:40:19
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:39:23

US3422280
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:40:19
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '10:09'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:39:23

US3422280
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:40:19
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered '15 Sep 2020 10:09'	System	15 Sep 2020 18:39:23

US3422280
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:40:19
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:39:23

US3422280
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:40:19
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:39:23

US3422280
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:40:19
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:39:23

US3422280
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:40:19
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered empty.	System	15 Sep 2020 18:39:23

US3422280
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:39:27

US3422280
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered '1'	System	15 Sep 2020 18:39:27

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US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T11:13:47', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '3facbf46-3dc8-4e9e-bd94-67c27d08acad'	System	15 Sep 2020 16:14:07
User entered 'Yes (Y)'	System	15 Sep 2020 16:14:07

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T11:13:52', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '3facbf46-3dc8-4e9e-bd94-67c27d08acad'	System	15 Sep 2020 16:14:07
User entered '98.8'	System	15 Sep 2020 16:14:07

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T11:13:57', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '3facbf46-3dc8-4e9e-bd94-67c27d08acad'	System	15 Sep 2020 16:14:07
User entered 'No (N)'	System	15 Sep 2020 16:14:07

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T11:14:01', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '3facbf46-3dc8-4e9e-bd94-67c27d08acad'	System	15 Sep 2020 16:14:07
User entered '15 Sep 2020 11:14'	System	15 Sep 2020 16:14:07

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '15 Sep 2020 11:01'	System	15 Sep 2020 15:43:59

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US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '15 Sep 2020 13:31'	System	15 Sep 2020 15:43:59

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US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T19:29:27', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'bbdb939a-4086-4381-abdd-f94cb436cd21'	System	16 Sep 2020 00:29:38
User entered 'Yes (Y)'	System	16 Sep 2020 00:29:38

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T19:29:31', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'bbdb939a-4086-4381-abdd-f94cb436cd21'	System	16 Sep 2020 00:29:38
User entered '98.0'	System	16 Sep 2020 00:29:38

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T19:29:33', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'bbdb939a-4086-4381-abdd-f94cb436cd21'	System	16 Sep 2020 00:29:38
User entered 'No (N)'	System	16 Sep 2020 00:29:38

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T19:29:36', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'bbdb939a-4086-4381-abdd-f94cb436cd21'	System	16 Sep 2020 00:29:38
User entered '15 Sep 2020 19:29'	System	16 Sep 2020 00:29:38

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US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '15 Sep 2020 14:26'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0804916

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

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US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 2'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:40:19
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-16T20:08:51', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '3c1f1427-d665-4490-8425-db3b9a8fca0f'	System	17 Sep 2020 01:09:03
User entered 'Yes (Y)'	System	17 Sep 2020 01:09:03

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US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:40:19
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-16T20:08:54', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '3c1f1427-d665-4490-8425-db3b9a8fca0f'	System	17 Sep 2020 01:09:03
User entered '98.6'	System	17 Sep 2020 01:09:03

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:40:19
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-16T20:08:56', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '3c1f1427-d665-4490-8425-db3b9a8fca0f'	System	17 Sep 2020 01:09:03
User entered 'No (N)'	System	17 Sep 2020 01:09:03

FDA-CBER-2022-1614-0804921

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-16T20:08:59', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '3c1f1427-d665-4490-8425-db3b9a8fca0f'	System	17 Sep 2020 01:09:03
User entered '16 Sep 2020 20:08'	System	17 Sep 2020 01:09:03

FDA-CBER-2022-1614-0804922

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0804923

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 3'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:40:19
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-17T20:02:58', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'cfc7c454-8d40-4c82-a28a-8407e6a019e0'	System	18 Sep 2020 01:03:12
User entered 'Yes (Y)'	System	18 Sep 2020 01:03:12

FDA-CBER-2022-1614-0804926

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:40:19
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-17T20:03:04', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'cfc7c454-8d40-4c82-a28a-8407e6a019e0'	System	18 Sep 2020 01:03:12
User entered '97.8'	System	18 Sep 2020 01:03:12

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:40:19
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-17T20:03:07', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'cfc7c454-8d40-4c82-a28a-8407e6a019e0'	System	18 Sep 2020 01:03:12
User entered 'No (N)'	System	18 Sep 2020 01:03:12

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-17T20:03:10', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'cfc7c454-8d40-4c82-a28a-8407e6a019e0'	System	18 Sep 2020 01:03:12
User entered '17 Sep 2020 20:03'	System	18 Sep 2020 01:03:12

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0804930

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0804931

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 4'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:40:19
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-18T20:01:49', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'de8e84d9-219a-4d3a-a090-79aeb563b2ab'	System	19 Sep 2020 01:02:11
User entered 'Yes (Y)'	System	19 Sep 2020 01:02:11

FDA-CBER-2022-1614-0804933

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:40:19
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-18T20:02:03', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'de8e84d9-219a-4d3a-a090-79aeb563b2ab'	System	19 Sep 2020 01:02:11
User entered '97.9'	System	19 Sep 2020 01:02:11

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:40:19
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-18T20:02:06', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'de8e84d9-219a-4d3a-a090-79aeb563b2ab'	System	19 Sep 2020 01:02:11
User entered 'No (N)'	System	19 Sep 2020 01:02:11

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-18T20:02:09', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'de8e84d9-219a-4d3a-a090-79aeb563b2ab'	System	19 Sep 2020 01:02:11
User entered '18 Sep 2020 20:02'	System	19 Sep 2020 01:02:11

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0804937

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0804938

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 5'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:40:19
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-19T20:03:40', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'eabddf1d-1444-48a0-aa1f-2670497b480b'	System	20 Sep 2020 01:03:57
User entered 'Yes (Y)'	System	20 Sep 2020 01:03:57

FDA-CBER-2022-1614-0804940

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:40:19
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-19T20:03:46', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'eabddf1d-1444-48a0-aa1f-2670497b480b'	System	20 Sep 2020 01:03:57
User entered '97.2'	System	20 Sep 2020 01:03:57

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:40:19
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-19T20:03:48', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'eabddf1d-1444-48a0-aa1f-2670497b480b'	System	20 Sep 2020 01:03:57
User entered 'No (N)'	System	20 Sep 2020 01:03:57

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-19T20:03:53', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'eabddf1d-1444-48a0-aa1f-2670497b480b'	System	20 Sep 2020 01:03:57
User entered '19 Sep 2020 20:03'	System	20 Sep 2020 01:03:57

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0804944

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0804945

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 6'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:40:19
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-20T20:07:12', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ff0bcb17-6f3c-49e8-b605-3096227aede5'	System	21 Sep 2020 01:07:26
User entered 'Yes (Y)'	System	21 Sep 2020 01:07:26

FDA-CBER-2022-1614-0804947

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:40:19
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-20T20:07:15', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ff0bcb17-6f3c-49e8-b605-3096227aede5'	System	21 Sep 2020 01:07:26
User entered '97.7'	System	21 Sep 2020 01:07:26

FDA-CBER-2022-1614-0804948

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:40:19
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-20T20:07:17', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ff0bcb17-6f3c-49e8-b605-3096227aede5'	System	21 Sep 2020 01:07:26
User entered 'No (N)'	System	21 Sep 2020 01:07:26

FDA-CBER-2022-1614-0804949

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-20T20:07:21', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ff0bcb17-6f3c-49e8-b605-3096227aede5'	System	21 Sep 2020 01:07:26
User entered '20 Sep 2020 20:07'	System	21 Sep 2020 01:07:26

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0804951

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0804952

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 7'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:40:19
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-21T20:02:10', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '4d84e689-96d6-44f6-998f-978dd007b407'	System	22 Sep 2020 01:02:21
User entered 'Yes (Y)'	System	22 Sep 2020 01:02:21

FDA-CBER-2022-1614-0804954

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:40:19
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-21T20:02:13', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '4d84e689-96d6-44f6-998f-978dd007b407'	System	22 Sep 2020 01:02:21
User entered '97.8'	System	22 Sep 2020 01:02:21

FDA-CBER-2022-1614-0804955

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:40:19
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-21T20:02:15', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '4d84e689-96d6-44f6-998f-978dd007b407'	System	22 Sep 2020 01:02:21
User entered 'No (N)'	System	22 Sep 2020 01:02:21

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-21T20:02:20', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '4d84e689-96d6-44f6-998f-978dd007b407'	System	22 Sep 2020 01:02:21
User entered '21 Sep 2020 20:02'	System	22 Sep 2020 01:02:21

FDA-CBER-2022-1614-0804957

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0804958

US3422280
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0804959

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0804960

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T11:14:09', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '9737c312-e385-4ca7-8924-99f9c3624530'	System	15 Sep 2020 16:15:06
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 16:15:06

FDA-CBER-2022-1614-0804961

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T11:14:36', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '9737c312-e385-4ca7-8924-99f9c3624530'	System	15 Sep 2020 16:15:06
User entered 'No (N)'	System	15 Sep 2020 16:15:06

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T11:14:42', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '9737c312-e385-4ca7-8924-99f9c3624530'	System	15 Sep 2020 16:15:06
User entered 'No (N)'	System	15 Sep 2020 16:15:06

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T11:14:55', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '9737c312-e385-4ca7-8924-99f9c3624530'	System	15 Sep 2020 16:15:06
User entered 'None (1)'	System	15 Sep 2020 16:15:06

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US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T11:15:03', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '9737c312-e385-4ca7-8924-99f9c3624530'	System	15 Sep 2020 16:15:06
User entered '15 Sep 2020 11:15'	System	15 Sep 2020 16:15:06

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US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '15 Sep 2020 11:01'	System	15 Sep 2020 15:43:59

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US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '15 Sep 2020 13:31'	System	15 Sep 2020 15:43:59

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US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T19:28:10', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ec6cfe3a-4322-41bf-89f7-2af68c9241a8'	System	16 Sep 2020 00:28:41
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 00:28:41

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T19:28:13', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ec6cfe3a-4322-41bf-89f7-2af68c9241a8'	System	16 Sep 2020 00:28:41
User entered 'No (N)'	System	16 Sep 2020 00:28:41

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T19:28:24', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ec6cfe3a-4322-41bf-89f7-2af68c9241a8'	System	16 Sep 2020 00:28:41
User entered 'No (N)'	System	16 Sep 2020 00:28:41

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US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T19:28:33', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ec6cfe3a-4322-41bf-89f7-2af68c9241a8'	System	16 Sep 2020 00:28:41
User entered 'None (1)'	System	16 Sep 2020 00:28:41

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T19:28:38', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ec6cfe3a-4322-41bf-89f7-2af68c9241a8'	System	16 Sep 2020 00:28:41
User entered '15 Sep 2020 19:28'	System	16 Sep 2020 00:28:41

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US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '15 Sep 2020 14:26'	System	15 Sep 2020 15:43:59

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US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0804975

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 2'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0804976

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:40:19
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-16T20:09:03', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'fae01618-3556-46a4-badc-e05a1e979714'	System	17 Sep 2020 01:09:22
User entered 'Does not interfere with activity (2)'	System	17 Sep 2020 01:09:22

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:40:19
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-16T20:09:05', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'fae01618-3556-46a4-badc-e05a1e979714'	System	17 Sep 2020 01:09:22
User entered 'No (N)'	System	17 Sep 2020 01:09:22

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:40:19
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-16T20:09:07', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'fae01618-3556-46a4-badc-e05a1e979714'	System	17 Sep 2020 01:09:22
User entered 'No (N)'	System	17 Sep 2020 01:09:22

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US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:40:19
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-16T20:09:14', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'fae01618-3556-46a4-badc-e05a1e979714'	System	17 Sep 2020 01:09:22
User entered 'None (1)'	System	17 Sep 2020 01:09:22

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-16T20:09:16', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'fae01618-3556-46a4-badc-e05a1e979714'	System	17 Sep 2020 01:09:22
User entered '16 Sep 2020 20:09'	System	17 Sep 2020 01:09:22

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

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US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 3'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:40:19
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-17T20:03:14', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '7c54eb48-4528-48f8-9f69-9981adc684c7'	System	18 Sep 2020 01:03:30
User entered 'None (1)'	System	18 Sep 2020 01:03:30

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:40:19
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-17T20:03:16', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '7c54eb48-4528-48f8-9f69-9981adc684c7'	System	18 Sep 2020 01:03:30
User entered 'No (N)'	System	18 Sep 2020 01:03:30

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:40:19
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-17T20:03:18', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '7c54eb48-4528-48f8-9f69-9981adc684c7'	System	18 Sep 2020 01:03:30
User entered 'No (N)'	System	18 Sep 2020 01:03:30

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:40:19
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-17T20:03:24', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '7c54eb48-4528-48f8-9f69-9981adc684c7'	System	18 Sep 2020 01:03:30
User entered 'None (1)'	System	18 Sep 2020 01:03:30

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-17T20:03:27', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '7c54eb48-4528-48f8-9f69-9981adc684c7'	System	18 Sep 2020 01:03:30
User entered '17 Sep 2020 20:03'	System	18 Sep 2020 01:03:30

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US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

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US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 4'	System	15 Sep 2020 15:43:59

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US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:40:19
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-18T20:01:04', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '77e752d8-7090-4c7d-90b6-a0a60bd60778'	System	19 Sep 2020 01:01:20
User entered 'None (1)'	System	19 Sep 2020 01:01:20

FDA-CBER-2022-1614-0804993

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:40:19
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-18T20:01:07', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '77e752d8-7090-4c7d-90b6-a0a60bd60778'	System	19 Sep 2020 01:01:20
User entered 'No (N)'	System	19 Sep 2020 01:01:20

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:40:19
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-18T20:01:09', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '77e752d8-7090-4c7d-90b6-a0a60bd60778'	System	19 Sep 2020 01:01:20
User entered 'No (N)'	System	19 Sep 2020 01:01:20

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:40:19
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-18T20:01:11', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '77e752d8-7090-4c7d-90b6-a0a60bd60778'	System	19 Sep 2020 01:01:20
User entered 'None (1)'	System	19 Sep 2020 01:01:20

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-18T20:01:15', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '77e752d8-7090-4c7d-90b6-a0a60bd60778'	System	19 Sep 2020 01:01:20
User entered '18 Sep 2020 20:01'	System	19 Sep 2020 01:01:20

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 15:43:59

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US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0804999

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 5'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:40:19
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-19T20:03:02', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ce6fb4c0-a82a-4f2d-925a-3ad540257810'	System	20 Sep 2020 01:03:17
User entered 'None (1)'	System	20 Sep 2020 01:03:17

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:40:19
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-19T20:03:04', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ce6fb4c0-a82a-4f2d-925a-3ad540257810'	System	20 Sep 2020 01:03:17
User entered 'No (N)'	System	20 Sep 2020 01:03:17

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:40:19
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-19T20:03:06', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ce6fb4c0-a82a-4f2d-925a-3ad540257810'	System	20 Sep 2020 01:03:17
User entered 'No (N)'	System	20 Sep 2020 01:03:17

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:40:19
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-19T20:03:08', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ce6fb4c0-a82a-4f2d-925a-3ad540257810'	System	20 Sep 2020 01:03:17
User entered 'None (1)'	System	20 Sep 2020 01:03:17

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-19T20:03:12', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ce6fb4c0-a82a-4f2d-925a-3ad540257810'	System	20 Sep 2020 01:03:17
User entered '19 Sep 2020 20:03'	System	20 Sep 2020 01:03:17

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 6'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:40:19
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-20T20:07:23', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '0d7a7645-81e8-4a2d-b61b-fba4275ff0ef'	System	21 Sep 2020 01:07:43
User entered 'None (1)'	System	21 Sep 2020 01:07:43

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:40:19
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-20T20:07:26', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '0d7a7645-81e8-4a2d-b61b-fba4275ff0ef'	System	21 Sep 2020 01:07:43
User entered 'No (N)'	System	21 Sep 2020 01:07:43

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:40:19
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-20T20:07:28', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '0d7a7645-81e8-4a2d-b61b-fba4275ff0ef'	System	21 Sep 2020 01:07:43
User entered 'No (N)'	System	21 Sep 2020 01:07:43

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:40:19
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-20T20:07:30', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '0d7a7645-81e8-4a2d-b61b-fba4275ff0ef'	System	21 Sep 2020 01:07:43
User entered 'None (1)'	System	21 Sep 2020 01:07:43

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-20T20:07:39', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '0d7a7645-81e8-4a2d-b61b-fba4275ff0ef'	System	21 Sep 2020 01:07:43
User entered '20 Sep 2020 20:07'	System	21 Sep 2020 01:07:43

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US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0805015

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 7'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0805016

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:40:19
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-21T20:02:23', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '91294af3-c17f-49a3-b816-d5865a76699b'	System	22 Sep 2020 01:02:38
User entered 'None (1)'	System	22 Sep 2020 01:02:38

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:40:19
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-21T20:02:25', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '91294af3-c17f-49a3-b816-d5865a76699b'	System	22 Sep 2020 01:02:38
User entered 'No (N)'	System	22 Sep 2020 01:02:38

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:40:19
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-21T20:02:28', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '91294af3-c17f-49a3-b816-d5865a76699b'	System	22 Sep 2020 01:02:38
User entered 'No (N)'	System	22 Sep 2020 01:02:38

FDA-CBER-2022-1614-0805019

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:40:19
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-21T20:02:29', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '91294af3-c17f-49a3-b816-d5865a76699b'	System	22 Sep 2020 01:02:38
User entered 'None (1)'	System	22 Sep 2020 01:02:38

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-21T20:02:32', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '91294af3-c17f-49a3-b816-d5865a76699b'	System	22 Sep 2020 01:02:38
User entered '21 Sep 2020 20:02'	System	22 Sep 2020 01:02:38

FDA-CBER-2022-1614-0805021

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0805023

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 15:43:59

FDA-CBER-2022-1614-0805024

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T11:15:10', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '6e65bcad-c367-4809-a54f-ced2e75b88a4'	System	15 Sep 2020 16:15:39
User entered 'None (0)'	System	15 Sep 2020 16:15:39

FDA-CBER-2022-1614-0805025

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T11:15:13', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '6e65bcad-c367-4809-a54f-ced2e75b88a4'	System	15 Sep 2020 16:15:39
User entered 'None (0)'	System	15 Sep 2020 16:15:39

FDA-CBER-2022-1614-0805026

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T11:15:16', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '6e65bcad-c367-4809-a54f-ced2e75b88a4'	System	15 Sep 2020 16:15:39
User entered 'None (0)'	System	15 Sep 2020 16:15:39

FDA-CBER-2022-1614-0805027

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T11:15:20', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '6e65bcad-c367-4809-a54f-ced2e75b88a4'	System	15 Sep 2020 16:15:39
User entered 'None (0)'	System	15 Sep 2020 16:15:39

FDA-CBER-2022-1614-0805028

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T11:15:23', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '6e65bcad-c367-4809-a54f-ced2e75b88a4'	System	15 Sep 2020 16:15:39
User entered 'None (0)'	System	15 Sep 2020 16:15:39

FDA-CBER-2022-1614-0805029

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T11:15:26', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '6e65bcad-c367-4809-a54f-ced2e75b88a4'	System	15 Sep 2020 16:15:39
User entered 'None (0)'	System	15 Sep 2020 16:15:39

FDA-CBER-2022-1614-0805030

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T11:15:29', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '6e65bcad-c367-4809-a54f-ced2e75b88a4'	System	15 Sep 2020 16:15:39
User entered 'No (N)'	System	15 Sep 2020 16:15:39

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T11:15:35', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '6e65bcad-c367-4809-a54f-ced2e75b88a4'	System	15 Sep 2020 16:15:39
User entered '15 Sep 2020 11:15'	System	15 Sep 2020 16:15:39

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '15 Sep 2020 11:01'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '15 Sep 2020 13:31'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T19:28:44', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'e40006ac-4398-4cb9-b323-b3af40c78980'	System	16 Sep 2020 00:29:17
User entered 'None (0)'	System	16 Sep 2020 00:29:17

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T19:28:49', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'e40006ac-4398-4cb9-b323-b3af40c78980'	System	16 Sep 2020 00:29:17
User entered 'None (0)'	System	16 Sep 2020 00:29:17

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T19:28:54', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'e40006ac-4398-4cb9-b323-b3af40c78980'	System	16 Sep 2020 00:29:17
User entered 'None (0)'	System	16 Sep 2020 00:29:17

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T19:28:58', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'e40006ac-4398-4cb9-b323-b3af40c78980'	System	16 Sep 2020 00:29:17
User entered 'None (0)'	System	16 Sep 2020 00:29:17

FDA-CBER-2022-1614-0805039

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T19:29:02', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'e40006ac-4398-4cb9-b323-b3af40c78980'	System	16 Sep 2020 00:29:17
User entered 'None (0)'	System	16 Sep 2020 00:29:17

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US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T19:29:04', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'e40006ac-4398-4cb9-b323-b3af40c78980'	System	16 Sep 2020 00:29:17
User entered 'None (0)'	System	16 Sep 2020 00:29:17

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US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T19:29:08', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'e40006ac-4398-4cb9-b323-b3af40c78980'	System	16 Sep 2020 00:29:17
User entered 'No (N)'	System	16 Sep 2020 00:29:17

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-15T19:29:15', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'e40006ac-4398-4cb9-b323-b3af40c78980'	System	16 Sep 2020 00:29:17
User entered '15 Sep 2020 19:29'	System	16 Sep 2020 00:29:17

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '15 Sep 2020 14:26'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 2'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-16T20:09:20', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '9404128a-8a18-4672-932d-184743d4bca9'	System	17 Sep 2020 01:10:37
User entered 'None (0)'	System	17 Sep 2020 01:10:37

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-16T20:09:22', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '9404128a-8a18-4672-932d-184743d4bca9'	System	17 Sep 2020 01:10:37
User entered 'None (0)'	System	17 Sep 2020 01:10:37

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-16T20:09:24', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '9404128a-8a18-4672-932d-184743d4bca9'	System	17 Sep 2020 01:10:37
User entered 'None (0)'	System	17 Sep 2020 01:10:37

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-16T20:09:25', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '9404128a-8a18-4672-932d-184743d4bca9'	System	17 Sep 2020 01:10:37
User entered 'None (0)'	System	17 Sep 2020 01:10:37

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-16T20:09:27', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '9404128a-8a18-4672-932d-184743d4bca9'	System	17 Sep 2020 01:10:37
User entered 'None (0)'	System	17 Sep 2020 01:10:37

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US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-16T20:09:29', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '9404128a-8a18-4672-932d-184743d4bca9'	System	17 Sep 2020 01:10:37
User entered 'None (0)'	System	17 Sep 2020 01:10:37

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-16T20:09:31', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '9404128a-8a18-4672-932d-184743d4bca9'	System	17 Sep 2020 01:10:37
User entered 'No (N)'	System	17 Sep 2020 01:10:37

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-16T20:10:35', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '9404128a-8a18-4672-932d-184743d4bca9'	System	17 Sep 2020 01:10:37
User entered '16 Sep 2020 20:10'	System	17 Sep 2020 01:10:37

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 15:43:59

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US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 3'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-17T20:03:32', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '67214592-35f4-4b2a-a44c-b0c64a223700'	System	18 Sep 2020 01:03:47
User entered 'None (0)'	System	18 Sep 2020 01:03:47

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-17T20:03:34', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '67214592-35f4-4b2a-a44c-b0c64a223700'	System	18 Sep 2020 01:03:47
User entered 'None (0)'	System	18 Sep 2020 01:03:47

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-17T20:03:35', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '67214592-35f4-4b2a-a44c-b0c64a223700'	System	18 Sep 2020 01:03:47
User entered 'None (0)'	System	18 Sep 2020 01:03:47

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-17T20:03:37', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '67214592-35f4-4b2a-a44c-b0c64a223700'	System	18 Sep 2020 01:03:47
User entered 'None (0)'	System	18 Sep 2020 01:03:47

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-17T20:03:38', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '67214592-35f4-4b2a-a44c-b0c64a223700'	System	18 Sep 2020 01:03:47
User entered 'None (0)'	System	18 Sep 2020 01:03:47

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-17T20:03:39', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '67214592-35f4-4b2a-a44c-b0c64a223700'	System	18 Sep 2020 01:03:47
User entered 'None (0)'	System	18 Sep 2020 01:03:47

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-17T20:03:41', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '67214592-35f4-4b2a-a44c-b0c64a223700'	System	18 Sep 2020 01:03:47
User entered 'No (N)'	System	18 Sep 2020 01:03:47

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-17T20:03:43', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '67214592-35f4-4b2a-a44c-b0c64a223700'	System	18 Sep 2020 01:03:47
User entered '17 Sep 2020 20:03'	System	18 Sep 2020 01:03:47

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 4'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-18T20:00:38', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '3f783cfb-ba0c-4e40-8640-9a24be4209e9'	System	19 Sep 2020 01:01:02
User entered 'No interference with activity (1)'	System	19 Sep 2020 01:01:02

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-18T20:00:44', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '3f783cfb-ba0c-4e40-8640-9a24be4209e9'	System	19 Sep 2020 01:01:02
User entered 'None (0)'	System	19 Sep 2020 01:01:02

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US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-18T20:00:46', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '3f783cfb-ba0c-4e40-8640-9a24be4209e9'	System	19 Sep 2020 01:01:02
User entered 'None (0)'	System	19 Sep 2020 01:01:02

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US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-18T20:00:49', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '3f783cfb-ba0c-4e40-8640-9a24be4209e9'	System	19 Sep 2020 01:01:02
User entered 'None (0)'	System	19 Sep 2020 01:01:02

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-18T20:00:51', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '3f783cfb-ba0c-4e40-8640-9a24be4209e9'	System	19 Sep 2020 01:01:02
User entered 'None (0)'	System	19 Sep 2020 01:01:02

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US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-18T20:00:53', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '3f783cfb-ba0c-4e40-8640-9a24be4209e9'	System	19 Sep 2020 01:01:02
User entered 'None (0)'	System	19 Sep 2020 01:01:02

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-18T20:00:56', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '3f783cfb-ba0c-4e40-8640-9a24be4209e9'	System	19 Sep 2020 01:01:02
User entered 'No (N)'	System	19 Sep 2020 01:01:02

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US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-18T20:00:58', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '3f783cfb-ba0c-4e40-8640-9a24be4209e9'	System	19 Sep 2020 01:01:02
User entered '18 Sep 2020 20:00'	System	19 Sep 2020 01:01:02

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US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 15:43:59

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US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 5'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-19T20:03:16', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '80cee136-5ec4-4857-9c80-4b2114d57f60'	System	20 Sep 2020 01:03:36
User entered 'None (0)'	System	20 Sep 2020 01:03:36

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-19T20:03:18', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '80cee136-5ec4-4857-9c80-4b2114d57f60'	System	20 Sep 2020 01:03:36
User entered 'None (0)'	System	20 Sep 2020 01:03:36

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-19T20:03:20', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '80cee136-5ec4-4857-9c80-4b2114d57f60'	System	20 Sep 2020 01:03:36
User entered 'None (0)'	System	20 Sep 2020 01:03:36

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-19T20:03:21', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '80cee136-5ec4-4857-9c80-4b2114d57f60'	System	20 Sep 2020 01:03:36
User entered 'None (0)'	System	20 Sep 2020 01:03:36

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-19T20:03:23', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '80cee136-5ec4-4857-9c80-4b2114d57f60'	System	20 Sep 2020 01:03:36
User entered 'None (0)'	System	20 Sep 2020 01:03:36

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US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-19T20:03:24', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '80cee136-5ec4-4857-9c80-4b2114d57f60'	System	20 Sep 2020 01:03:36
User entered 'None (0)'	System	20 Sep 2020 01:03:36

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-19T20:03:27', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '80cee136-5ec4-4857-9c80-4b2114d57f60'	System	20 Sep 2020 01:03:36
User entered 'No (N)'	System	20 Sep 2020 01:03:36

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-19T20:03:32', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '80cee136-5ec4-4857-9c80-4b2114d57f60'	System	20 Sep 2020 01:03:36
User entered '19 Sep 2020 20:03'	System	20 Sep 2020 01:03:36

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 15:43:59

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US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

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US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 6'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-20T20:07:42', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '31c372a0-344f-45d7-b760-13e973b7e107'	System	21 Sep 2020 01:07:56
User entered 'None (0)'	System	21 Sep 2020 01:07:56

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US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-20T20:07:44', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '31c372a0-344f-45d7-b760-13e973b7e107'	System	21 Sep 2020 01:07:56
User entered 'None (0)'	System	21 Sep 2020 01:07:56

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-20T20:07:45', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '31c372a0-344f-45d7-b760-13e973b7e107'	System	21 Sep 2020 01:07:56
User entered 'None (0)'	System	21 Sep 2020 01:07:56

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-20T20:07:46', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '31c372a0-344f-45d7-b760-13e973b7e107'	System	21 Sep 2020 01:07:56
User entered 'None (0)'	System	21 Sep 2020 01:07:56

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-20T20:07:48', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '31c372a0-344f-45d7-b760-13e973b7e107'	System	21 Sep 2020 01:07:56
User entered 'None (0)'	System	21 Sep 2020 01:07:56

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US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-20T20:07:49', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '31c372a0-344f-45d7-b760-13e973b7e107'	System	21 Sep 2020 01:07:56
User entered 'None (0)'	System	21 Sep 2020 01:07:56

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-20T20:07:51', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '31c372a0-344f-45d7-b760-13e973b7e107'	System	21 Sep 2020 01:07:56
User entered 'No (N)'	System	21 Sep 2020 01:07:56

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-20T20:07:55', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '31c372a0-344f-45d7-b760-13e973b7e107'	System	21 Sep 2020 01:07:56
User entered '20 Sep 2020 20:07'	System	21 Sep 2020 01:07:56

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 7'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-21T20:02:35', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '6accecd8-7184-44fa-b89f-f590ed39fe27'	System	22 Sep 2020 01:02:47
User entered 'None (0)'	System	22 Sep 2020 01:02:47

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-21T20:02:36', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '6accecd8-7184-44fa-b89f-f590ed39fe27'	System	22 Sep 2020 01:02:47
User entered 'None (0)'	System	22 Sep 2020 01:02:47

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-21T20:02:37', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '6accecd8-7184-44fa-b89f-f590ed39fe27'	System	22 Sep 2020 01:02:47
User entered 'None (0)'	System	22 Sep 2020 01:02:47

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-21T20:02:38', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '6accecd8-7184-44fa-b89f-f590ed39fe27'	System	22 Sep 2020 01:02:47
User entered 'None (0)'	System	22 Sep 2020 01:02:47

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-21T20:02:39', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '6accecd8-7184-44fa-b89f-f590ed39fe27'	System	22 Sep 2020 01:02:47
User entered 'None (0)'	System	22 Sep 2020 01:02:47

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-21T20:02:40', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '6accecd8-7184-44fa-b89f-f590ed39fe27'	System	22 Sep 2020 01:02:47
User entered 'None (0)'	System	22 Sep 2020 01:02:47

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-21T20:02:43', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '6accecd8-7184-44fa-b89f-f590ed39fe27'	System	22 Sep 2020 01:02:47
User entered 'No (N)'	System	22 Sep 2020 01:02:47

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-09-21T20:02:45', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '6accecd8-7184-44fa-b89f-f590ed39fe27'	System	22 Sep 2020 01:02:47
User entered '21 Sep 2020 20:02'	System	22 Sep 2020 01:02:47

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 15:43:59

US3422280
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 15:43:59

US3422280
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 22:12:47

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US3422280
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 22:12:47

US3422280
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 22:12:47

US3422280
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 22:12:47

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US3422280
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 22:12:54

US3422280
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered '1'	System	22 Sep 2020 22:12:54

US3422280
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 19:26:01

US3422280
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 19:26:01

US3422280
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Sep 2020 19:26:01

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US3422280
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 19:26:01

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US3422280
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 21:04:11

US3422280
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User entered '1'	System	06 Oct 2020 21:04:11

US3422280
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 21:04:30

US3422280
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '6 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 21:04:30

US3422280
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Oct 2020 21:04:30

US3422280
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 21:04:30

US3422280
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 21:04:36

US3422280
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User entered '1'	System	06 Oct 2020 21:04:36

US3422280
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Yes (Y)'	April Hanlotxomphou (b) (4)	16 Oct 2020 14:05:02

US3422280
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '16 Oct 2020'	April Hanlotxomphou (b) (4)	16 Oct 2020 14:05:02

US3422280
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Clinic (Clinic)'	April Hanlotxomphou (b) (4)	16 Oct 2020 14:05:02

US3422280
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'VISIT2'	System	16 Oct 2020 14:05:02

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User accepted default value 'Pre-Dose (PREDOSE)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

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US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '16 Oct 2020'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '8:21'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered '16 Oct 2020 8:21'	System	26 Oct 2020 13:40:47

FDA-CBER-2022-1614-0805138

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '98.6' F	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Oral (Oral)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

FDA-CBER-2022-1614-0805140

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

FDA-CBER-2022-1614-0805141

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '78'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

FDA-CBER-2022-1614-0805142

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'bpm'	System	26 Oct 2020 13:40:47

FDA-CBER-2022-1614-0805143

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '16'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'breaths/min'	System	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '105'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'mmHg'	System	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '72'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:40:19
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'mmHg'	System	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User accepted default value 'Post-Dose (POSTDOSE)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 13:40:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 13:40:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:52
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 13:40:47
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '16 Oct 2020'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '9:25'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered '16 Oct 2020 9:25'	System	26 Oct 2020 13:40:47

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US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '98.4' F	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Oral (Oral)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '81'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'bpm'	System	26 Oct 2020 13:40:47

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US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '16'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'breaths/min'	System	26 Oct 2020 13:40:47

FDA-CBER-2022-1614-0805161

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '106'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'mmHg'	System	26 Oct 2020 13:40:47

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US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '80'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:40:47

FDA-CBER-2022-1614-0805164

US3422280
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:40:19
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'mmHg'	System	26 Oct 2020 13:40:47

US3422280
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:40:19
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:41:09

US3422280
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:40:19
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '16 Oct 2020'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:41:09

US3422280
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:41:22

US3422280
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '16 Oct 2020'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:41:22

US3422280
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Urine (URINE)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:41:22

US3422280
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Negative (NEGATIVE)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:41:22

US3422280
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:41:22

US3422280
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:41:22

US3422280
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:41:22

US3422280
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:40:19
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered empty.	System	26 Oct 2020 13:41:22

FDA-CBER-2022-1614-0805175

US3422280
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:40:19
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Yes (Y)'	April Hanlotxomphou (b) (4)	16 Oct 2020 14:05:22

US3422280
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:40:19
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	April Hanlotxomphou (b) (4)	16 Oct 2020 14:05:22

US3422280
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:40:19
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	April Hanlotxomphou (b) (4)	16 Oct 2020 14:05:22

US3422280
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:40:19
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'MRNA-1273 OR PLACEBO'	System	16 Oct 2020 14:05:22

US3422280
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:40:19
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '16 Oct 2020'	April Hanlotxomphou (b) (4)	16 Oct 2020 14:05:22

US3422280
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:40:19
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '08:50'	April Hanlotxomphou (b) (4)	16 Oct 2020 14:05:22

US3422280
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:40:19
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered '16 Oct 2020 08:50'	System	16 Oct 2020 14:05:22

US3422280
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:40:19
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Left Arm (LEFT ARM)'	April Hanlotxomphou (b) (4)	16 Oct 2020 14:05:22

US3422280
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:40:19
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'ONCE'	System	16 Oct 2020 14:05:22

US3422280
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:40:19
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'INTRAMUSCULAR'	System	16 Oct 2020 14:05:22

US3422280
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:40:19
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:41:38

US3422280
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:40:19
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '16 Oct 2020'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:41:38

US3422280
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:40:19
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '8:35'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:41:38

US3422280
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:40:19
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered '16 Oct 2020 8:35'	System	26 Oct 2020 13:41:38

US3422280
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 11 Aug 2021 22:40:19
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '16 Oct 2020'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:41:51

US3422280
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:40:19
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:41:51

US3422280
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:40:19
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:41:51

US3422280
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:40:19
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '8:37'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:41:51

US3422280
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:40:19
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered '16 Oct 2020 8:37'	System	26 Oct 2020 13:41:51

US3422280
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:40:19
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:41:51

US3422280
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:40:19
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:41:51

US3422280
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:40:19
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:41:51

US3422280
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:40:19
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered empty.	System	26 Oct 2020 13:41:51

US3422280
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:41:55

US3422280
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered '1'	System	26 Oct 2020 13:41:55

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 14:05:22

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US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T09:20:47', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'df1ad44f-e20d-410c-8b0b-7b1430869f4d'	System	16 Oct 2020 14:21:01
User entered 'Yes (Y)'	System	16 Oct 2020 14:21:01

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US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T09:20:51', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'df1ad44f-e20d-410c-8b0b-7b1430869f4d'	System	16 Oct 2020 14:21:01
User entered '98.4'	System	16 Oct 2020 14:21:01

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T09:20:54', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'df1ad44f-e20d-410c-8b0b-7b1430869f4d'	System	16 Oct 2020 14:21:01
User entered 'No (N)'	System	16 Oct 2020 14:21:01

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T09:20:57', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'df1ad44f-e20d-410c-8b0b-7b1430869f4d'	System	16 Oct 2020 14:21:01
User entered '16 Oct 2020 09:20'	System	16 Oct 2020 14:21:01

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '16 Oct 2020 09:10'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '16 Oct 2020 11:40'	System	16 Oct 2020 14:05:22

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US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T18:48:45', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '24f33374-7b93-41f5-906c-a804480d5a1e'	System	16 Oct 2020 23:49:08
User entered 'Yes (Y)'	System	16 Oct 2020 23:49:08

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US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T18:48:48', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '24f33374-7b93-41f5-906c-a804480d5a1e'	System	16 Oct 2020 23:49:08
User entered '98.2'	System	16 Oct 2020 23:49:08

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T18:48:52', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '24f33374-7b93-41f5-906c-a804480d5a1e'	System	16 Oct 2020 23:49:08
User entered 'Yes (Y)'	System	16 Oct 2020 23:49:08

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US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	08 Nov 2020 04:44:30
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'yes' (Site from System).	Naomi Kown (b) (4) (b) (4)	21 Oct 2020 14:53:11
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	16 Oct 2020 23:49:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T18:48:58', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '24f33374-7b93-41f5-906c-a804480d5a1e'	System	16 Oct 2020 23:49:08
User entered '1'	System	16 Oct 2020 23:49:08

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T18:48:58', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '24f33374-7b93-41f5-906c-a804480d5a1e'	System	16 Oct 2020 23:49:08
User entered '0'	System	16 Oct 2020 23:49:08

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US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T18:49:02', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '24f33374-7b93-41f5-906c-a804480d5a1e'	System	16 Oct 2020 23:49:08
User entered '16 Oct 2020 18:49'	System	16 Oct 2020 23:49:08

FDA-CBER-2022-1614-0805214

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '16 Oct 2020 12:35'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805216

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 2'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:40:19
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:51:23', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'fd8dfba1-ab08-48fe-91f9-7b5f1191173f'	System	17 Oct 2020 21:52:47
User entered 'Yes (Y)'	System	17 Oct 2020 21:52:47

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:40:19
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:52:17', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'fd8dfba1-ab08-48fe-91f9-7b5f1191173f'	System	17 Oct 2020 21:52:47
User entered '99.3'	System	17 Oct 2020 21:52:47

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:40:19
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:52:23', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'fd8dfba1-ab08-48fe-91f9-7b5f1191173f'	System	17 Oct 2020 21:52:47
User entered 'Yes (Y)'	System	17 Oct 2020 21:52:47

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US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:40:19
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	08 Nov 2020 04:44:35
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'yes' (Site from System).	Naomi Kown (b) (4) (b) (4)	21 Oct 2020 14:54:24
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	17 Oct 2020 21:52:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:52:26', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'fd8dfba1-ab08-48fe-91f9-7b5f1191173f'	System	17 Oct 2020 21:52:47
User entered '1'	System	17 Oct 2020 21:52:47

FDA-CBER-2022-1614-0805221

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:40:19
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:52:26', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'fd8dfba1-ab08-48fe-91f9-7b5f1191173f'	System	17 Oct 2020 21:52:47
User entered '0'	System	17 Oct 2020 21:52:47

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:52:45', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'fd8dfba1-ab08-48fe-91f9-7b5f1191173f'	System	17 Oct 2020 21:52:47
User entered '17 Oct 2020 16:52'	System	17 Oct 2020 21:52:47

FDA-CBER-2022-1614-0805223

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805224

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805225

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 3'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805226

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:40:19
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T19:58:43', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '4d0206c6-01fa-48f6-a0ed-5d148d227e56'	System	19 Oct 2020 00:59:04
User entered 'Yes (Y)'	System	19 Oct 2020 00:59:04

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:40:19
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T19:58:47', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '4d0206c6-01fa-48f6-a0ed-5d148d227e56'	System	19 Oct 2020 00:59:04
User entered '97.2'	System	19 Oct 2020 00:59:04

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:40:19
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T19:58:54', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '4d0206c6-01fa-48f6-a0ed-5d148d227e56'	System	19 Oct 2020 00:59:04
User entered 'Yes (Y)'	System	19 Oct 2020 00:59:04

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:40:19
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	08 Nov 2020 04:44:40
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'yes' (Site from System).	Naomi Kown (b) (4) (b) (4)	21 Oct 2020 14:54:48
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	19 Oct 2020 00:59:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T19:59:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '4d0206c6-01fa-48f6-a0ed-5d148d227e56'	System	19 Oct 2020 00:59:04
User entered '1'	System	19 Oct 2020 00:59:04

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:40:19
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T19:59:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '4d0206c6-01fa-48f6-a0ed-5d148d227e56'	System	19 Oct 2020 00:59:04
User entered '0'	System	19 Oct 2020 00:59:04

FDA-CBER-2022-1614-0805231

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T19:59:02', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '4d0206c6-01fa-48f6-a0ed-5d148d227e56'	System	19 Oct 2020 00:59:04
User entered '18 Oct 2020 19:59'	System	19 Oct 2020 00:59:04

FDA-CBER-2022-1614-0805232

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805233

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805234

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 4'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:40:19
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-19T21:06:56', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '7132c379-c560-4282-a673-c979bcd229fb'	System	20 Oct 2020 02:07:08
User entered 'Yes (Y)'	System	20 Oct 2020 02:07:08

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:40:19
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-19T21:06:59', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '7132c379-c560-4282-a673-c979bcd229fb'	System	20 Oct 2020 02:07:08
User entered '97.2'	System	20 Oct 2020 02:07:08

FDA-CBER-2022-1614-0805237

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:40:19
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-19T21:07:03', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '7132c379-c560-4282-a673-c979bcd229fb'	System	20 Oct 2020 02:07:08
User entered 'No (N)'	System	20 Oct 2020 02:07:08

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-19T21:07:05', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '7132c379-c560-4282-a673-c979bcd229fb'	System	20 Oct 2020 02:07:08
User entered '19 Oct 2020 21:07'	System	20 Oct 2020 02:07:08

FDA-CBER-2022-1614-0805239

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805240

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805241

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 5'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805242

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:40:19
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-20T19:18:39', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '2e9780d4-5a46-4b48-a62a-6f4e676d664a'	System	21 Oct 2020 00:18:52
User entered 'Yes (Y)'	System	21 Oct 2020 00:18:52

FDA-CBER-2022-1614-0805243

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:40:19
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-20T19:18:43', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '2e9780d4-5a46-4b48-a62a-6f4e676d664a'	System	21 Oct 2020 00:18:52
User entered '98.7'	System	21 Oct 2020 00:18:52

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:40:19
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-20T19:18:45', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '2e9780d4-5a46-4b48-a62a-6f4e676d664a'	System	21 Oct 2020 00:18:52
User entered 'No (N)'	System	21 Oct 2020 00:18:52

FDA-CBER-2022-1614-0805245

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-20T19:18:49', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '2e9780d4-5a46-4b48-a62a-6f4e676d664a'	System	21 Oct 2020 00:18:52
User entered '20 Oct 2020 19:18'	System	21 Oct 2020 00:18:52

FDA-CBER-2022-1614-0805246

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805247

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 6'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805249

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:40:19
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-21T20:02:37', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'f33a136a-5449-401d-a99b-74b97b21192f'	System	22 Oct 2020 01:02:48
User entered 'Yes (Y)'	System	22 Oct 2020 01:02:48

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:40:19
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-21T20:02:41', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'f33a136a-5449-401d-a99b-74b97b21192f'	System	22 Oct 2020 01:02:48
User entered '98.2'	System	22 Oct 2020 01:02:48

FDA-CBER-2022-1614-0805251

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:40:19
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-21T20:02:43', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'f33a136a-5449-401d-a99b-74b97b21192f'	System	22 Oct 2020 01:02:48
User entered 'No (N)'	System	22 Oct 2020 01:02:48

FDA-CBER-2022-1614-0805252

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-21T20:02:46', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'f33a136a-5449-401d-a99b-74b97b21192f'	System	22 Oct 2020 01:02:48
User entered '21 Oct 2020 20:02'	System	22 Oct 2020 01:02:48

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805254

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805255

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 7'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805256

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:40:19
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-22T21:10:18', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '3c71581a-3d7c-44ae-8ae5-89bd7c63c671'	System	23 Oct 2020 02:10:31
User entered 'Yes (Y)'	System	23 Oct 2020 02:10:31

FDA-CBER-2022-1614-0805257

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:40:19
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-22T21:10:24', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '3c71581a-3d7c-44ae-8ae5-89bd7c63c671'	System	23 Oct 2020 02:10:31
User entered '98.4'	System	23 Oct 2020 02:10:31

FDA-CBER-2022-1614-0805258

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:40:19
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-22T21:10:27', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '3c71581a-3d7c-44ae-8ae5-89bd7c63c671'	System	23 Oct 2020 02:10:31
User entered 'No (N)'	System	23 Oct 2020 02:10:31

FDA-CBER-2022-1614-0805259

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-22T21:10:29', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '3c71581a-3d7c-44ae-8ae5-89bd7c63c671'	System	23 Oct 2020 02:10:31
User entered '22 Oct 2020 21:10'	System	23 Oct 2020 02:10:31

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805261

US3422280
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805262

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T09:21:31', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'd21a3183-8ba2-4645-af6a-0f26e524b2ba'	System	16 Oct 2020 14:21:48
User entered 'None (1)'	System	16 Oct 2020 14:21:48

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US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T09:21:36', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'd21a3183-8ba2-4645-af6a-0f26e524b2ba'	System	16 Oct 2020 14:21:48
User entered 'No (N)'	System	16 Oct 2020 14:21:48

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T09:21:39', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'd21a3183-8ba2-4645-af6a-0f26e524b2ba'	System	16 Oct 2020 14:21:48
User entered 'No (N)'	System	16 Oct 2020 14:21:48

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US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T09:21:43', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'd21a3183-8ba2-4645-af6a-0f26e524b2ba'	System	16 Oct 2020 14:21:48
User entered 'None (1)'	System	16 Oct 2020 14:21:48

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T09:21:45', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'd21a3183-8ba2-4645-af6a-0f26e524b2ba'	System	16 Oct 2020 14:21:48
User entered '16 Oct 2020 09:21'	System	16 Oct 2020 14:21:48

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US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '16 Oct 2020 09:10'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '16 Oct 2020 11:40'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805270

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T18:49:28', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'a22f0ecc-051f-47f1-a1d1-71e4c181c8aa'	System	16 Oct 2020 23:49:45
User entered 'Any use of prescription pain reliever or prevents daily activity (4)'	System	16 Oct 2020 23:49:45

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T18:49:30', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'a22f0ecc-051f-47f1-a1d1-71e4c181c8aa'	System	16 Oct 2020 23:49:45
User entered 'No (N)'	System	16 Oct 2020 23:49:45

FDA-CBER-2022-1614-0805273

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T18:49:35', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'a22f0ecc-051f-47f1-a1d1-71e4c181c8aa'	System	16 Oct 2020 23:49:45
User entered 'No (N)'	System	16 Oct 2020 23:49:45

FDA-CBER-2022-1614-0805274

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T18:49:40', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'a22f0ecc-051f-47f1-a1d1-71e4c181c8aa'	System	16 Oct 2020 23:49:45
User entered 'None (1)'	System	16 Oct 2020 23:49:45

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T18:49:42', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'a22f0ecc-051f-47f1-a1d1-71e4c181c8aa'	System	16 Oct 2020 23:49:45
User entered '16 Oct 2020 18:49'	System	16 Oct 2020 23:49:45

FDA-CBER-2022-1614-0805276

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '16 Oct 2020 12:35'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805277

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805278

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 2'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805279

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:40:19
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:53:35', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '9f375aa3-a92e-4ed4-9795-77662251bf5b'	System	17 Oct 2020 21:55:41
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	17 Oct 2020 21:55:41

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:40:19
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:53:39', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '9f375aa3-a92e-4ed4-9795-77662251bf5b'	System	17 Oct 2020 21:55:41
User entered 'Yes (Y)'	System	17 Oct 2020 21:55:41

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US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:40:19
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:54:52', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '9f375aa3-a92e-4ed4-9795-77662251bf5b'	System	17 Oct 2020 21:55:41
User entered '110'	System	17 Oct 2020 21:55:41

FDA-CBER-2022-1614-0805282

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:40:19
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:54:54', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '9f375aa3-a92e-4ed4-9795-77662251bf5b'	System	17 Oct 2020 21:55:41
User entered 'Yes (Y)'	System	17 Oct 2020 21:55:41

FDA-CBER-2022-1614-0805283

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:40:19
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:55:18', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '9f375aa3-a92e-4ed4-9795-77662251bf5b'	System	17 Oct 2020 21:55:41
User entered '110'	System	17 Oct 2020 21:55:41

FDA-CBER-2022-1614-0805284

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:40:19
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:55:33', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '9f375aa3-a92e-4ed4-9795-77662251bf5b'	System	17 Oct 2020 21:55:41
User entered 'None (1)'	System	17 Oct 2020 21:55:41

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:55:37', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '9f375aa3-a92e-4ed4-9795-77662251bf5b'	System	17 Oct 2020 21:55:41
User entered '17 Oct 2020 16:55'	System	17 Oct 2020 21:55:41

FDA-CBER-2022-1614-0805286

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805288

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 3'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805289

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:40:19
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T19:59:17', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'd19ddce6-cadc-478f-9498-51b8ce5e9e49'	System	19 Oct 2020 00:59:41
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	19 Oct 2020 00:59:41

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:40:19
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T19:59:19', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'd19ddce6-cadc-478f-9498-51b8ce5e9e49'	System	19 Oct 2020 00:59:41
User entered 'Yes (Y)'	System	19 Oct 2020 00:59:41

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:40:19
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T19:59:25', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'd19ddce6-cadc-478f-9498-51b8ce5e9e49'	System	19 Oct 2020 00:59:41
User entered '110'	System	19 Oct 2020 00:59:41

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:40:19
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T19:59:27', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'd19ddce6-cadc-478f-9498-51b8ce5e9e49'	System	19 Oct 2020 00:59:41
User entered 'Yes (Y)'	System	19 Oct 2020 00:59:41

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:40:19
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T19:59:31', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'd19ddce6-cadc-478f-9498-51b8ce5e9e49'	System	19 Oct 2020 00:59:41
User entered '110'	System	19 Oct 2020 00:59:41

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:40:19
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T19:59:35', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'd19ddce6-cadc-478f-9498-51b8ce5e9e49'	System	19 Oct 2020 00:59:41
User entered 'None (1)'	System	19 Oct 2020 00:59:41

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US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T19:59:39', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'd19ddce6-cadc-478f-9498-51b8ce5e9e49'	System	19 Oct 2020 00:59:41
User entered '18 Oct 2020 19:59'	System	19 Oct 2020 00:59:41

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 4'	System	16 Oct 2020 14:05:22

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US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:40:19
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-19T21:07:12', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '495dbdee-deda-450b-b9b6-fc6c24b99d43'	System	20 Oct 2020 02:07:51
User entered 'Does not interfere with activity (2)'	System	20 Oct 2020 02:07:51

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:40:19
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-19T21:07:14', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '495dbdee-deda-450b-b9b6-fc6c24b99d43'	System	20 Oct 2020 02:07:51
User entered 'Yes (Y)'	System	20 Oct 2020 02:07:51

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:40:19
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-19T21:07:20', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '495dbdee-deda-450b-b9b6-fc6c24b99d43'	System	20 Oct 2020 02:07:51
User entered '90'	System	20 Oct 2020 02:07:51

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:40:19
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-19T21:07:26', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '495dbdee-deda-450b-b9b6-fc6c24b99d43'	System	20 Oct 2020 02:07:51
User entered 'No (N)'	System	20 Oct 2020 02:07:51

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:40:19
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-19T21:07:29', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '495dbdee-deda-450b-b9b6-fc6c24b99d43'	System	20 Oct 2020 02:07:51
User entered 'None (1)'	System	20 Oct 2020 02:07:51

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-19T21:07:47', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '495dbdee-deda-450b-b9b6-fc6c24b99d43'	System	20 Oct 2020 02:07:51
User entered '19 Oct 2020 21:07'	System	20 Oct 2020 02:07:51

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US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 5'	System	16 Oct 2020 14:05:22

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US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:40:19
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-20T19:20:08', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '4acdeb00-561f-46cb-9fce-73dc4a3080bd'	System	21 Oct 2020 00:20:38
User entered 'None (1)'	System	21 Oct 2020 00:20:38

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:40:19
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-20T19:20:10', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '4acdeb00-561f-46cb-9fce-73dc4a3080bd'	System	21 Oct 2020 00:20:38
User entered 'Yes (Y)'	System	21 Oct 2020 00:20:38

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:40:19
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-20T19:20:16', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '4acdeb00-561f-46cb-9fce-73dc4a3080bd'	System	21 Oct 2020 00:20:38
User entered '900'	System	21 Oct 2020 00:20:38

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:40:19
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-20T19:20:25', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '4acdeb00-561f-46cb-9fce-73dc4a3080bd'	System	21 Oct 2020 00:20:38
User entered 'No (N)'	System	21 Oct 2020 00:20:38

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:40:19
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-20T19:20:33', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '4acdeb00-561f-46cb-9fce-73dc4a3080bd'	System	21 Oct 2020 00:20:38
User entered 'None (1)'	System	21 Oct 2020 00:20:38

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-20T19:20:35', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '4acdeb00-561f-46cb-9fce-73dc4a3080bd'	System	21 Oct 2020 00:20:38
User entered '20 Oct 2020 19:20'	System	21 Oct 2020 00:20:38

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US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 14:05:22

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US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

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US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 6'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:40:19
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-21T20:02:50', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'c2fa9909-c532-4b68-ac4d-7ed8120fdd6e'	System	22 Oct 2020 01:03:01
User entered 'None (1)'	System	22 Oct 2020 01:03:01

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:40:19
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-21T20:02:52', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'c2fa9909-c532-4b68-ac4d-7ed8120fdd6e'	System	22 Oct 2020 01:03:01
User entered 'No (N)'	System	22 Oct 2020 01:03:01

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:40:19
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-21T20:02:54', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'c2fa9909-c532-4b68-ac4d-7ed8120fdd6e'	System	22 Oct 2020 01:03:01
User entered 'No (N)'	System	22 Oct 2020 01:03:01

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:40:19
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-21T20:02:56', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'c2fa9909-c532-4b68-ac4d-7ed8120fdd6e'	System	22 Oct 2020 01:03:01
User entered 'None (1)'	System	22 Oct 2020 01:03:01

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-21T20:02:59', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'c2fa9909-c532-4b68-ac4d-7ed8120fdd6e'	System	22 Oct 2020 01:03:01
User entered '21 Oct 2020 20:02'	System	22 Oct 2020 01:03:01

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US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805323

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805324

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 7'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:40:19
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-22T21:10:33', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ad86eae9-53d1-4e99-8ca8-a7b45d0c77b3'	System	23 Oct 2020 02:10:43
User entered 'None (1)'	System	23 Oct 2020 02:10:43

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:40:19
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-22T21:10:35', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ad86eae9-53d1-4e99-8ca8-a7b45d0c77b3'	System	23 Oct 2020 02:10:43
User entered 'No (N)'	System	23 Oct 2020 02:10:43

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:40:19
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-22T21:10:37', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ad86eae9-53d1-4e99-8ca8-a7b45d0c77b3'	System	23 Oct 2020 02:10:43
User entered 'No (N)'	System	23 Oct 2020 02:10:43

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:40:19
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-22T21:10:39', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ad86eae9-53d1-4e99-8ca8-a7b45d0c77b3'	System	23 Oct 2020 02:10:43
User entered 'None (1)'	System	23 Oct 2020 02:10:43

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:40:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-22T21:10:41', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ad86eae9-53d1-4e99-8ca8-a7b45d0c77b3'	System	23 Oct 2020 02:10:43
User entered '22 Oct 2020 21:10'	System	23 Oct 2020 02:10:43

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805331

US3422280
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805332

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T09:21:49', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '2f839782-db42-4b3b-9051-bb00295affd7'	System	16 Oct 2020 14:22:03
User entered 'None (0)'	System	16 Oct 2020 14:22:03

FDA-CBER-2022-1614-0805334

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T09:21:50', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '2f839782-db42-4b3b-9051-bb00295affd7'	System	16 Oct 2020 14:22:03
User entered 'None (0)'	System	16 Oct 2020 14:22:03

FDA-CBER-2022-1614-0805335

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T09:21:52', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '2f839782-db42-4b3b-9051-bb00295affd7'	System	16 Oct 2020 14:22:03
User entered 'None (0)'	System	16 Oct 2020 14:22:03

FDA-CBER-2022-1614-0805336

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T09:21:53', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '2f839782-db42-4b3b-9051-bb00295affd7'	System	16 Oct 2020 14:22:03
User entered 'None (0)'	System	16 Oct 2020 14:22:03

FDA-CBER-2022-1614-0805337

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T09:21:55', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '2f839782-db42-4b3b-9051-bb00295affd7'	System	16 Oct 2020 14:22:03
User entered 'None (0)'	System	16 Oct 2020 14:22:03

FDA-CBER-2022-1614-0805338

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T09:21:56', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '2f839782-db42-4b3b-9051-bb00295affd7'	System	16 Oct 2020 14:22:03
User entered 'None (0)'	System	16 Oct 2020 14:22:03

FDA-CBER-2022-1614-0805339

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T09:21:59', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '2f839782-db42-4b3b-9051-bb00295affd7'	System	16 Oct 2020 14:22:03
User entered 'No (N)'	System	16 Oct 2020 14:22:03

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T09:22:02', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '2f839782-db42-4b3b-9051-bb00295affd7'	System	16 Oct 2020 14:22:03
User entered '16 Oct 2020 09:22'	System	16 Oct 2020 14:22:03

FDA-CBER-2022-1614-0805341

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '16 Oct 2020 09:10'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805342

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '16 Oct 2020 11:40'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805343

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T18:49:46', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '38aa3b6d-7e2f-4dde-b233-8531899f7d5c'	System	16 Oct 2020 23:50:05
User entered 'None (0)'	System	16 Oct 2020 23:50:05

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T18:49:48', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '38aa3b6d-7e2f-4dde-b233-8531899f7d5c'	System	16 Oct 2020 23:50:05
User entered 'None (0)'	System	16 Oct 2020 23:50:05

FDA-CBER-2022-1614-0805346

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T18:49:50', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '38aa3b6d-7e2f-4dde-b233-8531899f7d5c'	System	16 Oct 2020 23:50:05
User entered 'None (0)'	System	16 Oct 2020 23:50:05

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T18:49:52', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '38aa3b6d-7e2f-4dde-b233-8531899f7d5c'	System	16 Oct 2020 23:50:05
User entered 'None (0)'	System	16 Oct 2020 23:50:05

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T18:49:55', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '38aa3b6d-7e2f-4dde-b233-8531899f7d5c'	System	16 Oct 2020 23:50:05
User entered 'None (0)'	System	16 Oct 2020 23:50:05

FDA-CBER-2022-1614-0805349

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T18:49:57', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '38aa3b6d-7e2f-4dde-b233-8531899f7d5c'	System	16 Oct 2020 23:50:05
User entered 'None (0)'	System	16 Oct 2020 23:50:05

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T18:49:59', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '38aa3b6d-7e2f-4dde-b233-8531899f7d5c'	System	16 Oct 2020 23:50:05
User entered 'No (N)'	System	16 Oct 2020 23:50:05

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-16T18:50:02', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '38aa3b6d-7e2f-4dde-b233-8531899f7d5c'	System	16 Oct 2020 23:50:05
User entered '16 Oct 2020 18:50'	System	16 Oct 2020 23:50:05

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '16 Oct 2020 12:35'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805353

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805354

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 2'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:53:02', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'dce006ad-cbf0-419b-9f38-9ecebbd7bdd9'	System	17 Oct 2020 21:53:31
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	17 Oct 2020 21:53:31

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:53:06', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'dce006ad-cbf0-419b-9f38-9ecebbd7bdd9'	System	17 Oct 2020 21:53:31
User entered 'Some interference with activity (2)'	System	17 Oct 2020 21:53:31

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:53:09', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'dce006ad-cbf0-419b-9f38-9ecebbd7bdd9'	System	17 Oct 2020 21:53:31
User entered 'Some interference with activity (2)'	System	17 Oct 2020 21:53:31

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:53:12', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'dce006ad-cbf0-419b-9f38-9ecebbd7bdd9'	System	17 Oct 2020 21:53:31
User entered 'Some interference with activity (2)'	System	17 Oct 2020 21:53:31

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:53:19', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'dce006ad-cbf0-419b-9f38-9ecebbd7bdd9'	System	17 Oct 2020 21:53:31
User entered 'None (0)'	System	17 Oct 2020 21:53:31

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US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:53:21', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'dce006ad-cbf0-419b-9f38-9ecebbd7bdd9'	System	17 Oct 2020 21:53:31
User entered 'No interference with activity (1)'	System	17 Oct 2020 21:53:31

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:53:24', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'dce006ad-cbf0-419b-9f38-9ecebbd7bdd9'	System	17 Oct 2020 21:53:31
User entered 'No (N)'	System	17 Oct 2020 21:53:31

FDA-CBER-2022-1614-0805362

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-17T16:53:26', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'dce006ad-cbf0-419b-9f38-9ecebbd7bdd9'	System	17 Oct 2020 21:53:31
User entered '17 Oct 2020 16:53'	System	17 Oct 2020 21:53:31

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805364

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805365

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 3'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805366

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T19:59:44', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'fcba7faf-d810-4c09-9b87-3fffcfdd36af'	System	19 Oct 2020 01:00:05
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	19 Oct 2020 01:00:05

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T19:59:47', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'fcba7faf-d810-4c09-9b87-3fffcfdd36af'	System	19 Oct 2020 01:00:05
User entered 'None (0)'	System	19 Oct 2020 01:00:05

FDA-CBER-2022-1614-0805368

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T19:59:50', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'fcba7faf-d810-4c09-9b87-3fffcfdd36af'	System	19 Oct 2020 01:00:05
User entered 'None (0)'	System	19 Oct 2020 01:00:05

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T19:59:52', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'fcba7faf-d810-4c09-9b87-3fffcfdd36af'	System	19 Oct 2020 01:00:05
User entered 'None (0)'	System	19 Oct 2020 01:00:05

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T19:59:54', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'fcba7faf-d810-4c09-9b87-3fffcfdd36af'	System	19 Oct 2020 01:00:05
User entered 'None (0)'	System	19 Oct 2020 01:00:05

FDA-CBER-2022-1614-0805371

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T19:59:56', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'fcba7faf-d810-4c09-9b87-3fffcfdd36af'	System	19 Oct 2020 01:00:05
User entered 'None (0)'	System	19 Oct 2020 01:00:05

FDA-CBER-2022-1614-0805372

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T19:59:59', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'fcba7faf-d810-4c09-9b87-3fffcfdd36af'	System	19 Oct 2020 01:00:05
User entered 'No (N)'	System	19 Oct 2020 01:00:05

FDA-CBER-2022-1614-0805373

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-18T20:00:02', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'fcba7faf-d810-4c09-9b87-3fffcfdd36af'	System	19 Oct 2020 01:00:05
User entered '18 Oct 2020 20:00'	System	19 Oct 2020 01:00:05

FDA-CBER-2022-1614-0805374

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805375

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805376

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 4'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-19T21:07:52', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '2a92833c-7a6a-4474-b093-1889b4522b1b'	System	20 Oct 2020 02:27:49
User entered 'None (0)'	System	20 Oct 2020 02:27:49

FDA-CBER-2022-1614-0805378

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-19T21:07:54', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '2a92833c-7a6a-4474-b093-1889b4522b1b'	System	20 Oct 2020 02:27:49
User entered 'None (0)'	System	20 Oct 2020 02:27:49

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-19T21:07:56', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '2a92833c-7a6a-4474-b093-1889b4522b1b'	System	20 Oct 2020 02:27:49
User entered 'None (0)'	System	20 Oct 2020 02:27:49

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-19T21:07:58', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '2a92833c-7a6a-4474-b093-1889b4522b1b'	System	20 Oct 2020 02:27:49
User entered 'None (0)'	System	20 Oct 2020 02:27:49

FDA-CBER-2022-1614-0805381

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-19T21:08:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '2a92833c-7a6a-4474-b093-1889b4522b1b'	System	20 Oct 2020 02:27:49
User entered 'None (0)'	System	20 Oct 2020 02:27:49

FDA-CBER-2022-1614-0805382

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-19T21:08:02', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '2a92833c-7a6a-4474-b093-1889b4522b1b'	System	20 Oct 2020 02:27:49
User entered 'None (0)'	System	20 Oct 2020 02:27:49

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-19T21:27:42', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '2a92833c-7a6a-4474-b093-1889b4522b1b'	System	20 Oct 2020 02:27:49
User entered 'No (N)'	System	20 Oct 2020 02:27:49

FDA-CBER-2022-1614-0805384

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-19T21:27:47', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '2a92833c-7a6a-4474-b093-1889b4522b1b'	System	20 Oct 2020 02:27:49
User entered '19 Oct 2020 21:27'	System	20 Oct 2020 02:27:49

FDA-CBER-2022-1614-0805385

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805386

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805387

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 5'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-20T19:18:53', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '345d6c0a-1f2a-44e0-9070-8eadb4488393'	System	21 Oct 2020 00:19:19
User entered 'None (0)'	System	21 Oct 2020 00:19:19

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-20T19:18:58', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '345d6c0a-1f2a-44e0-9070-8eadb4488393'	System	21 Oct 2020 00:19:19
User entered 'None (0)'	System	21 Oct 2020 00:19:19

FDA-CBER-2022-1614-0805390

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-20T19:19:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '345d6c0a-1f2a-44e0-9070-8eadb4488393'	System	21 Oct 2020 00:19:19
User entered 'None (0)'	System	21 Oct 2020 00:19:19

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-20T19:19:02', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '345d6c0a-1f2a-44e0-9070-8eadb4488393'	System	21 Oct 2020 00:19:19
User entered 'None (0)'	System	21 Oct 2020 00:19:19

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-20T19:19:06', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '345d6c0a-1f2a-44e0-9070-8eadb4488393'	System	21 Oct 2020 00:19:19
User entered 'None (0)'	System	21 Oct 2020 00:19:19

FDA-CBER-2022-1614-0805393

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-20T19:19:07', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '345d6c0a-1f2a-44e0-9070-8eadb4488393'	System	21 Oct 2020 00:19:19
User entered 'None (0)'	System	21 Oct 2020 00:19:19

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-20T19:19:09', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '345d6c0a-1f2a-44e0-9070-8eadb4488393'	System	21 Oct 2020 00:19:19
User entered 'No (N)'	System	21 Oct 2020 00:19:19

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-20T19:19:12', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '345d6c0a-1f2a-44e0-9070-8eadb4488393'	System	21 Oct 2020 00:19:19
User entered '20 Oct 2020 19:19'	System	21 Oct 2020 00:19:19

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805397

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 6'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-21T20:03:02', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '7a2d00a7-7679-4f96-b9db-826be44d9191'	System	22 Oct 2020 01:03:18
User entered 'None (0)'	System	22 Oct 2020 01:03:18

FDA-CBER-2022-1614-0805400

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-21T20:03:04', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '7a2d00a7-7679-4f96-b9db-826be44d9191'	System	22 Oct 2020 01:03:18
User entered 'None (0)'	System	22 Oct 2020 01:03:18

FDA-CBER-2022-1614-0805401

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-21T20:03:05', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '7a2d00a7-7679-4f96-b9db-826be44d9191'	System	22 Oct 2020 01:03:18
User entered 'None (0)'	System	22 Oct 2020 01:03:18

FDA-CBER-2022-1614-0805402

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-21T20:03:07', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '7a2d00a7-7679-4f96-b9db-826be44d9191'	System	22 Oct 2020 01:03:18
User entered 'None (0)'	System	22 Oct 2020 01:03:18

FDA-CBER-2022-1614-0805403

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-21T20:03:09', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '7a2d00a7-7679-4f96-b9db-826be44d9191'	System	22 Oct 2020 01:03:18
User entered 'None (0)'	System	22 Oct 2020 01:03:18

FDA-CBER-2022-1614-0805404

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-21T20:03:11', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '7a2d00a7-7679-4f96-b9db-826be44d9191'	System	22 Oct 2020 01:03:18
User entered 'None (0)'	System	22 Oct 2020 01:03:18

FDA-CBER-2022-1614-0805405

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-21T20:03:13', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '7a2d00a7-7679-4f96-b9db-826be44d9191'	System	22 Oct 2020 01:03:18
User entered 'No (N)'	System	22 Oct 2020 01:03:18

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-21T20:03:16', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '7a2d00a7-7679-4f96-b9db-826be44d9191'	System	22 Oct 2020 01:03:18
User entered '21 Oct 2020 20:03'	System	22 Oct 2020 01:03:18

FDA-CBER-2022-1614-0805407

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805408

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	16 Oct 2020 14:05:22
User entered 'Day 7'	System	16 Oct 2020 14:05:22

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-22T21:10:45', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '5407d4b7-4ea3-4f1c-98a6-6981ffd6fe85'	System	23 Oct 2020 02:11:00
User entered 'None (0)'	System	23 Oct 2020 02:11:00

FDA-CBER-2022-1614-0805411

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-22T21:10:46', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '5407d4b7-4ea3-4f1c-98a6-6981ffd6fe85'	System	23 Oct 2020 02:11:00
User entered 'None (0)'	System	23 Oct 2020 02:11:00

FDA-CBER-2022-1614-0805412

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-22T21:10:48', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '5407d4b7-4ea3-4f1c-98a6-6981ffd6fe85'	System	23 Oct 2020 02:11:00
User entered 'None (0)'	System	23 Oct 2020 02:11:00

FDA-CBER-2022-1614-0805413

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-22T21:10:49', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '5407d4b7-4ea3-4f1c-98a6-6981ffd6fe85'	System	23 Oct 2020 02:11:00
User entered 'None (0)'	System	23 Oct 2020 02:11:00

FDA-CBER-2022-1614-0805414

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-22T21:10:51', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '5407d4b7-4ea3-4f1c-98a6-6981ffd6fe85'	System	23 Oct 2020 02:11:00
User entered 'None (0)'	System	23 Oct 2020 02:11:00

FDA-CBER-2022-1614-0805415

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-22T21:10:52', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '5407d4b7-4ea3-4f1c-98a6-6981ffd6fe85'	System	23 Oct 2020 02:11:00
User entered 'None (0)'	System	23 Oct 2020 02:11:00

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-22T21:10:54', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '5407d4b7-4ea3-4f1c-98a6-6981ffd6fe85'	System	23 Oct 2020 02:11:00
User entered 'No (N)'	System	23 Oct 2020 02:11:00

FDA-CBER-2022-1614-0805417

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-10-22T21:10:57', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '5407d4b7-4ea3-4f1c-98a6-6981ffd6fe85'	System	23 Oct 2020 02:11:00
User entered '22 Oct 2020 21:10'	System	23 Oct 2020 02:11:00

FDA-CBER-2022-1614-0805418

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805419

US3422280
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:40:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 14:05:22

FDA-CBER-2022-1614-0805420

US3422280
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:42:12

FDA-CBER-2022-1614-0805421

US3422280
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '23 Oct 2020'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:42:12

US3422280
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Contact Made (CONTACT MADE)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:42:12

US3422280
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:42:12

US3422280
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:42:16

US3422280
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User entered '1'	System	26 Oct 2020 13:42:16

US3422280
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	30 Oct 2020 18:39:33

US3422280
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered '30 Oct 2020'	Cindy Trimmer (b) (4) (b) (4)	30 Oct 2020 18:39:33

US3422280
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Contact Made (CONTACT MADE)'	Cindy Trimmer (b) (4) (b) (4)	30 Oct 2020 18:39:33

FDA-CBER-2022-1614-0805429

US3422280
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	30 Oct 2020 18:39:33

US3422280
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	30 Oct 2020 18:39:25

FDA-CBER-2022-1614-0805431

US3422280
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:03:54
User entered '1'	System	30 Oct 2020 18:39:25

US3422280
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 16:02:28

FDA-CBER-2022-1614-0805433

US3422280
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	09 Dec 2020 09:28:12
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'NOVEMBER 5TH IS 51 DAYS FROM 15SEP2020, DAY 1. THIS IS WITHIN WINDOW' (Site from System).	April Hanlotxomphou (b) (4)	04 Dec 2020 18:25:04
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	17 Nov 2020 16:02:28
User entered '5 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 16:02:28

US3422280
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Nov 2020 16:02:28

FDA-CBER-2022-1614-0805435

US3422280
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 16:02:28

US3422280
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 16:02:42

US3422280
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered '1'	System	17 Nov 2020 16:02:42

US3422280
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 16:03:08

FDA-CBER-2022-1614-0805439

US3422280
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 16:03:08

US3422280
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Nov 2020 16:03:08

US3422280
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered 'VISIT3'	System	17 Nov 2020 16:03:08

FDA-CBER-2022-1614-0805442

US3422280
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 16:03:28

US3422280
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 16:03:28

FDA-CBER-2022-1614-0805444

US3422280
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 16:03:28

US3422280
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered empty.	System	17 Nov 2020 16:03:28

FDA-CBER-2022-1614-0805446

US3422280
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 16:03:28

US3422280
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 16:03:28

US3422280
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 16:03:28

US3422280
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 16:03:28

US3422280
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered empty.	System	17 Nov 2020 16:03:28

FDA-CBER-2022-1614-0805451

US3422280
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 16:03:28

US3422280
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered empty.	System	17 Nov 2020 16:03:28

US3422280
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 16:03:28

US3422280
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered empty.	System	17 Nov 2020 16:03:28

FDA-CBER-2022-1614-0805455

US3422280
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 16:03:28

US3422280
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered empty.	System	17 Nov 2020 16:03:28

FDA-CBER-2022-1614-0805457

US3422280
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00

FDA-CBER-2022-1614-0805458

US3422280
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00

FDA-CBER-2022-1614-0805459

US3422280
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:40:19
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 16:03:39

US3422280
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:40:19
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 16:03:39

US3422280
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:40:19
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 16:04:00

FDA-CBER-2022-1614-0805462

US3422280
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:40:19
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 16:04:00

US3422280
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:40:19
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered '08:10'	(b) (4), (b) (6)	17 Nov 2020 16:04:00

US3422280
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:40:19
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered '16 Nov 2020 08:10'	System	17 Nov 2020 16:04:00

US3422280
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	19 Feb 2021 20:54:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 16:04:09

US3422280
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered '1'	System	17 Nov 2020 16:04:09

FDA-CBER-2022-1614-0805467

US3422280
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered 'Day 64'	System	15 Sep 2020 15:43:59

US3422280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-11-17T12:00:19', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '142e25c9-2c44-4bbd-b5c9-1373e935b912'	System	17 Nov 2020 18:00:29
User entered 'No (N)'	System	17 Nov 2020 18:00:29

US3422280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-11-17T12:00:23', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '142e25c9-2c44-4bbd-b5c9-1373e935b912'	System	17 Nov 2020 18:00:29
User entered 'No (N)'	System	17 Nov 2020 18:00:29

US3422280
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-11-17T12:00:26', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '142e25c9-2c44-4bbd-b5c9-1373e935b912'	System	17 Nov 2020 18:00:29
User entered '17 Nov 2020 12:00:26'	System	17 Nov 2020 18:00:29

FDA-CBER-2022-1614-0805471

US3422280
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered '15 Nov 2020 00:01'	System	15 Sep 2020 15:43:59

US3422280
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 06:03:39
Data entry locked.	System	15 Sep 2020 15:43:59
User entered '19 Nov 2020 23:59'	System	15 Sep 2020 15:43:59

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-11-23T13:53:49', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '46a53b69-95fe-4905-a897-ddd9d52f7d86'	System	23 Nov 2020 19:53:58
User entered 'No (N)'	System	23 Nov 2020 19:53:58

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-11-23T13:53:51', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '46a53b69-95fe-4905-a897-ddd9d52f7d86'	System	23 Nov 2020 19:53:58
User entered 'No (N)'	System	23 Nov 2020 19:53:58

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-11-23T13:53:54', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '46a53b69-95fe-4905-a897-ddd9d52f7d86'	System	23 Nov 2020 19:53:58
User entered '23 Nov 2020 13:53:54'	System	23 Nov 2020 19:53:58

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-11-26T06:28:04', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '4ba80cce-8107-4fdc-9ae7-429fb34d11c4'	System	26 Nov 2020 12:28:19
User entered 'No (N)'	System	26 Nov 2020 12:28:19

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-11-26T06:28:13', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '4ba80cce-8107-4fdc-9ae7-429fb34d11c4'	System	26 Nov 2020 12:28:19
User entered 'No (N)'	System	26 Nov 2020 12:28:19

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-11-26T06:28:16', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '4ba80cce-8107-4fdc-9ae7-429fb34d11c4'	System	26 Nov 2020 12:28:19
User entered '26 Nov 2020 06:28:16'	System	26 Nov 2020 12:28:19

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-12-04T22:37:28', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'b1dc63c2-301d-470c-b221-1b2143e25ec7'	System	05 Dec 2020 04:37:49
User entered 'No (N)'	System	05 Dec 2020 04:37:49

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-12-04T22:37:44', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'b1dc63c2-301d-470c-b221-1b2143e25ec7'	System	05 Dec 2020 04:37:49
User entered 'No (N)'	System	05 Dec 2020 04:37:49

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-12-04T22:37:47', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'b1dc63c2-301d-470c-b221-1b2143e25ec7'	System	05 Dec 2020 04:37:49
User entered '04 Dec 2020 22:37:47'	System	05 Dec 2020 04:37:49

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-12-10T06:02:08', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ba45a2fe-498a-4342-af0d-75846dcbc9c2'	System	10 Dec 2020 12:02:17
User entered 'No (N)'	System	10 Dec 2020 12:02:17

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-12-10T06:02:11', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ba45a2fe-498a-4342-af0d-75846dcbc9c2'	System	10 Dec 2020 12:02:17
User entered 'No (N)'	System	10 Dec 2020 12:02:17

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-12-10T06:02:15', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ba45a2fe-498a-4342-af0d-75846dcbc9c2'	System	10 Dec 2020 12:02:17
User entered '10 Dec 2020 06:02:15'	System	10 Dec 2020 12:02:17

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-12-17T05:29:02', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'b9de15f9-f97b-4104-9cf2-e4a2efba1adc'	System	17 Dec 2020 11:29:10
User entered 'No (N)'	System	17 Dec 2020 11:29:10

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-12-17T05:29:04', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'b9de15f9-f97b-4104-9cf2-e4a2efba1adc'	System	17 Dec 2020 11:29:10
User entered 'No (N)'	System	17 Dec 2020 11:29:10

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-12-17T05:29:07', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'b9de15f9-f97b-4104-9cf2-e4a2efba1adc'	System	17 Dec 2020 11:29:10
User entered '17 Dec 2020 05:29:07'	System	17 Dec 2020 11:29:10

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-12-24T07:20:23', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '216424ef-28c2-4019-9f9c-96ff07f4ec3e'	System	24 Dec 2020 13:20:34
User entered 'No (N)'	System	24 Dec 2020 13:20:34

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-12-24T07:20:26', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '216424ef-28c2-4019-9f9c-96ff07f4ec3e'	System	24 Dec 2020 13:20:34
User entered 'No (N)'	System	24 Dec 2020 13:20:34

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-12-24T07:20:29', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '216424ef-28c2-4019-9f9c-96ff07f4ec3e'	System	24 Dec 2020 13:20:34
User entered '24 Dec 2020 07:20:29'	System	24 Dec 2020 13:20:34

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-12-31T06:51:06', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'd50c3ec1-1f58-4d78-aedc-9ef06601f7e6'	System	31 Dec 2020 12:51:13
User entered 'No (N)'	System	31 Dec 2020 12:51:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-12-31T06:51:09', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'd50c3ec1-1f58-4d78-aedc-9ef06601f7e6'	System	31 Dec 2020 12:51:13
User entered 'No (N)'	System	31 Dec 2020 12:51:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2020-12-31T06:51:12', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'd50c3ec1-1f58-4d78-aedc-9ef06601f7e6'	System	31 Dec 2020 12:51:13
User entered '31 Dec 2020 06:51:12'	System	31 Dec 2020 12:51:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-01-07T06:01:47', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '52506a6d-dc05-460e-a9ff-4034aca0808e'	System	07 Jan 2021 12:01:55
User entered 'No (N)'	System	07 Jan 2021 12:01:55

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-01-07T06:01:50', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '52506a6d-dc05-460e-a9ff-4034aca0808e'	System	07 Jan 2021 12:01:55
User entered 'No (N)'	System	07 Jan 2021 12:01:55

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-01-07T06:01:53', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '52506a6d-dc05-460e-a9ff-4034aca0808e'	System	07 Jan 2021 12:01:55
User entered '07 Jan 2021 06:01:53'	System	07 Jan 2021 12:01:55

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-01-16T12:33:26', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'b15f4068-a131-4626-bcbe-0c280851b429'	System	16 Jan 2021 18:33:38
User entered 'No (N)'	System	16 Jan 2021 18:33:38

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-01-16T12:33:29', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'b15f4068-a131-4626-bcbe-0c280851b429'	System	16 Jan 2021 18:33:38
User entered 'No (N)'	System	16 Jan 2021 18:33:38

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-01-16T12:33:31', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'b15f4068-a131-4626-bcbe-0c280851b429'	System	16 Jan 2021 18:33:38
User entered '16 Jan 2021 12:33:31'	System	16 Jan 2021 18:33:38

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-01-21T05:41:38', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'f3586789-27d8-4794-a39a-06745cbb1a9c'	System	21 Jan 2021 11:41:47
User entered 'No (N)'	System	21 Jan 2021 11:41:47

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-01-21T05:41:40', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'f3586789-27d8-4794-a39a-06745cbb1a9c'	System	21 Jan 2021 11:41:47
User entered 'No (N)'	System	21 Jan 2021 11:41:47

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-01-21T05:41:45', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'f3586789-27d8-4794-a39a-06745cbb1a9c'	System	21 Jan 2021 11:41:47
User entered '21 Jan 2021 05:41:45'	System	21 Jan 2021 11:41:47

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-01-28T05:05:06', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '89a03a70-5da9-49ad-8936-ab7ec9515baa'	System	01 Feb 2021 19:01:48
User entered 'No (N)'	System	01 Feb 2021 19:01:48

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-01-28T05:05:07', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '89a03a70-5da9-49ad-8936-ab7ec9515baa'	System	01 Feb 2021 19:01:48
User entered 'No (N)'	System	01 Feb 2021 19:01:48

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-01-28T05:05:12', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '89a03a70-5da9-49ad-8936-ab7ec9515baa'	System	01 Feb 2021 19:01:48
User entered '28 Jan 2021 05:05:12'	System	01 Feb 2021 19:01:48

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-02-06T12:00:29', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '497e7490-05e4-4c5c-b0f5-038deb25d8ed'	System	06 Feb 2021 18:01:00
User entered 'No (N)'	System	06 Feb 2021 18:01:00

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-02-06T12:00:30', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '497e7490-05e4-4c5c-b0f5-038deb25d8ed'	System	06 Feb 2021 18:01:00
User entered 'No (N)'	System	06 Feb 2021 18:01:00

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-02-06T12:00:33', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '497e7490-05e4-4c5c-b0f5-038deb25d8ed'	System	06 Feb 2021 18:01:00
User entered '06 Feb 2021 12:00:33'	System	06 Feb 2021 18:01:00

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-02-11T05:53:24', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'a10f7d82-8c1c-47a8-ab44-deabff632cfb'	System	11 Feb 2021 11:53:40
User entered 'No (N)'	System	11 Feb 2021 11:53:40

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-02-11T05:53:27', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'a10f7d82-8c1c-47a8-ab44-deabff632cfb'	System	11 Feb 2021 11:53:40
User entered 'No (N)'	System	11 Feb 2021 11:53:40

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-02-11T05:53:30', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'a10f7d82-8c1c-47a8-ab44-deabff632cfb'	System	11 Feb 2021 11:53:40
User entered '11 Feb 2021 05:53:30'	System	11 Feb 2021 11:53:40

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-02-18T01:24:35', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'd41eef5a-c73d-4ca7-844e-901688acc63b'	System	18 Feb 2021 07:24:42
User entered 'No (N)'	System	18 Feb 2021 07:24:42

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-02-18T01:24:38', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'd41eef5a-c73d-4ca7-844e-901688acc63b'	System	18 Feb 2021 07:24:42
User entered 'No (N)'	System	18 Feb 2021 07:24:42

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-02-18T01:24:41', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'd41eef5a-c73d-4ca7-844e-901688acc63b'	System	18 Feb 2021 07:24:42
User entered '18 Feb 2021 01:24:41'	System	18 Feb 2021 07:24:42

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-02-27T12:00:23-06:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'c3c2418c-f8a8-4406-b773-58d1eebe9c42'	System	27 Feb 2021 18:00:38
User entered 'No (N)'	System	27 Feb 2021 18:00:38

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-02-27T12:00:25-06:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'c3c2418c-f8a8-4406-b773-58d1eebe9c42'	System	27 Feb 2021 18:00:38
User entered 'No (N)'	System	27 Feb 2021 18:00:38

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-02-27T12:00:29-06:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'c3c2418c-f8a8-4406-b773-58d1eebe9c42'	System	27 Feb 2021 18:00:38
User entered '27 Feb 2021 18:00:29'	System	27 Feb 2021 18:00:38

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-03-04T04:53:33-06:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '5b080599-f084-47bb-9c63-484fd4bcff2e'	System	04 Mar 2021 10:53:46
User entered 'No (N)'	System	04 Mar 2021 10:53:46

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-03-04T04:53:38-06:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '5b080599-f084-47bb-9c63-484fd4bcff2e'	System	04 Mar 2021 10:53:46
User entered 'No (N)'	System	04 Mar 2021 10:53:46

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-03-04T04:53:41-06:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '5b080599-f084-47bb-9c63-484fd4bcff2e'	System	04 Mar 2021 10:53:46
User entered '04 Mar 2021 04:53:41'	System	04 Mar 2021 10:53:46

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-03-11T05:21:49-06:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '0f4a162c-de88-45cb-be38-3bab8e6348dd'	System	11 Mar 2021 11:21:57
User entered 'No (N)'	System	11 Mar 2021 11:21:57

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-03-11T05:21:52-06:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '0f4a162c-de88-45cb-be38-3bab8e6348dd'	System	11 Mar 2021 11:21:57
User entered 'No (N)'	System	11 Mar 2021 11:21:57

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-03-11T05:21:55-06:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '0f4a162c-de88-45cb-be38-3bab8e6348dd'	System	11 Mar 2021 11:21:57
User entered '11 Mar 2021 05:21:55'	System	11 Mar 2021 11:21:57

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-03-20T21:57:50-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '0a7f235f-f4c7-4209-9595-1c06c776f282'	System	21 Mar 2021 02:58:04
User entered 'No (N)'	System	21 Mar 2021 02:58:04

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-03-20T21:57:52-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '0a7f235f-f4c7-4209-9595-1c06c776f282'	System	21 Mar 2021 02:58:04
User entered 'No (N)'	System	21 Mar 2021 02:58:04

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-03-20T21:58:02-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '0a7f235f-f4c7-4209-9595-1c06c776f282'	System	21 Mar 2021 02:58:04
User entered '20 Mar 2021 21:58:02'	System	21 Mar 2021 02:58:04

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-03-27T12:00:29-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '32394c45-d32b-4adb-b508-2ab89c85a1e1'	System	27 Mar 2021 17:00:40
User entered 'No (N)'	System	27 Mar 2021 17:00:40

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-03-27T12:00:31-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '32394c45-d32b-4adb-b508-2ab89c85a1e1'	System	27 Mar 2021 17:00:40
User entered 'No (N)'	System	27 Mar 2021 17:00:40

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-03-27T12:00:33-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '32394c45-d32b-4adb-b508-2ab89c85a1e1'	System	27 Mar 2021 17:00:40
User entered '27 Mar 2021 12:00:33'	System	27 Mar 2021 17:00:40

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-04-01T04:11:06-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '97acd636-ed03-4cff-afbe-e3b7aac94cc0'	System	01 Apr 2021 09:11:14
User entered 'No (N)'	System	01 Apr 2021 09:11:14

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-04-01T04:11:08-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '97acd636-ed03-4cff-afbe-e3b7aac94cc0'	System	01 Apr 2021 09:11:14
User entered 'No (N)'	System	01 Apr 2021 09:11:14

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-04-01T04:11:12-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '97acd636-ed03-4cff-afbe-e3b7aac94cc0'	System	01 Apr 2021 09:11:14
User entered '01 Apr 2021 04:11:12'	System	01 Apr 2021 09:11:14

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-04-09T07:21:31-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '05822137-4490-43ac-9403-85a318edb667'	System	09 Apr 2021 12:22:10
User entered 'Yes (Y)'	System	09 Apr 2021 12:22:10

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-04-09T07:21:33-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '05822137-4490-43ac-9403-85a318edb667'	System	09 Apr 2021 12:22:10
User entered 'No (N)'	System	09 Apr 2021 12:22:10

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-04-09T07:21:36-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '05822137-4490-43ac-9403-85a318edb667'	System	09 Apr 2021 12:22:10
User entered 'No (N)'	System	09 Apr 2021 12:22:10

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-04-09T07:21:42-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '05822137-4490-43ac-9403-85a318edb667'	System	09 Apr 2021 12:22:10
User entered 'Yes (Y)'	System	09 Apr 2021 12:22:10

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Please 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-04-09T07:21:47-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '05822137-4490-43ac-9403-85a318edb667'	System	09 Apr 2021 12:22:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Apr 2021 12:22:10

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-04-09T07:21:49-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: '05822137-4490-43ac-9403-85a318edb667'	System	09 Apr 2021 12:22:10
User entered '09 Apr 2021 07:21:49'	System	09 Apr 2021 12:22:10

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-04-15T07:47:02-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ec1cea4d-6b1c-453f-9187-9833cdf33697'	System	15 Apr 2021 12:47:11
User entered 'No (N)'	System	15 Apr 2021 12:47:11

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-04-15T07:47:04-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ec1cea4d-6b1c-453f-9187-9833cdf33697'	System	15 Apr 2021 12:47:11
User entered 'No (N)'	System	15 Apr 2021 12:47:11

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-04-15T07:47:07-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'ec1cea4d-6b1c-453f-9187-9833cdf33697'	System	15 Apr 2021 12:47:11
User entered '15 Apr 2021 07:47:07'	System	15 Apr 2021 12:47:11

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-04-22T07:15:56-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'f4ec0c8f-97ce-4161-bfd7-c88dbfc481b0'	System	22 Apr 2021 12:16:04
User entered 'No (N)'	System	22 Apr 2021 12:16:04

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-04-22T07:15:57-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'f4ec0c8f-97ce-4161-bfd7-c88dbfc481b0'	System	22 Apr 2021 12:16:04
User entered 'No (N)'	System	22 Apr 2021 12:16:04

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-04-22T07:16:00-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'f4ec0c8f-97ce-4161-bfd7-c88dbfc481b0'	System	22 Apr 2021 12:16:04
User entered '22 Apr 2021 07:16:00'	System	22 Apr 2021 12:16:04

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 08:37:13

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-05-01T12:00:13-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'c2a9ede7-fb97-4df9-90d7-61559a576fe8'	System	01 May 2021 17:00:40
User entered 'Yes (Y)'	System	01 May 2021 17:00:40

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you been exposed to someone with 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-05-01T12:00:15-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'c2a9ede7-fb97-4df9-90d7-61559a576fe8'	System	01 May 2021 17:00:40
User entered 'No (N)'	System	01 May 2021 17:00:40

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-05-01T12:00:17-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'c2a9ede7-fb97-4df9-90d7-61559a576fe8'	System	01 May 2021 17:00:40
User entered 'No (N)'	System	01 May 2021 17:00:40

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-05-01T12:00:20-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'c2a9ede7-fb97-4df9-90d7-61559a576fe8'	System	01 May 2021 17:00:40
User entered 'Yes (Y)'	System	01 May 2021 17:00:40

US3422280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:19

Please 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 (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-05-01T12:00:23-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'c2a9ede7-fb97-4df9-90d7-61559a576fe8'	System	01 May 2021 17:00:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 May 2021 17:00:40

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-05-01T12:00:25-05:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'c2a9ede7-fb97-4df9-90d7-61559a576fe8'	System	01 May 2021 17:00:40
User entered '01 May 2021 12:00:25'	System	01 May 2021 17:00:40

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 08:37:13

US3422280
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:40:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:13
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 08:37:13

US3422280

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:40:19

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 03:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-03-04T04:53:48-06:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'a5a08e63-5e6d-4542-a2a1-1b06aa3405f1'	System	04 Mar 2021 10:54:05
User entered 'No (N)'	System	04 Mar 2021 10:54:05

US3422280
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary (1)
Generated On: 11 Aug 2021 22:40:19
Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 03:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (667E29EB-34B9-434B-B9F1-0C792A9779D4)', Time: '2021-03-04T04:53:51-06:00', User OID: 'PatientReportedOutcome (US3422280)', ODM File OID: 'a5a08e63-5e6d-4542-a2a1-1b06aa3405f1'	System	04 Mar 2021 10:54:05
User entered '04 Mar 2021 04:53:51'	System	04 Mar 2021 10:54:05

US3422280
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	05 Mar 2021 19:00:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 19:32:24

US3422280
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	05 Mar 2021 19:00:01
User entered '10 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 21:18:11
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Dec 2020 21:07:56
User entered '10 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 19:32:24

US3422280
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	05 Mar 2021 19:00:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Dec 2020 19:32:24

FDA-CBER-2022-1614-0805871

US3422280
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	05 Mar 2021 19:00:01
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:32:24

FDA-CBER-2022-1614-0805872

US3422280
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	05 Mar 2021 19:00:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 19:32:32

US3422280
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:04:00
User entered '1'	System	10 Dec 2020 19:32:32

US3422280
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 16:43:46

US3422280
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '13 Jan 2021'	(b) (4), (b) (6)	13 Jan 2021 16:43:46

US3422280
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Jan 2021 16:43:46

US3422280
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 16:43:46

US3422280
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 16:43:34

US3422280
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User entered '1'	System	13 Jan 2021 16:43:34

FDA-CBER-2022-1614-0805880

US3422280
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 19:56:55

FDA-CBER-2022-1614-0805881

US3422280
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '12 Feb 2021'	(b) (4), (b) (6)	12 Feb 2021 19:56:55

US3422280
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Feb 2021 19:56:55

FDA-CBER-2022-1614-0805883

US3422280
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 19:56:55

FDA-CBER-2022-1614-0805884

US3422280
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 19:57:01

FDA-CBER-2022-1614-0805885

US3422280
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User entered '1'	System	12 Feb 2021 19:57:01

FDA-CBER-2022-1614-0805886

US3422280
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 17:39:06

US3422280
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '15 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 17:40:18
User entered '16 Mar 2021'	(b) (4), (b) (6)	16 Mar 2021 17:39:06

FDA-CBER-2022-1614-0805888

US3422280
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Mar 2021 17:39:06

US3422280
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:40:19
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:39:06

US3422280
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 17:39:13

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US3422280
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User entered '1'	System	16 Mar 2021 17:39:13

FDA-CBER-2022-1614-0805892

US3422280
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	31 Mar 2021 15:40:49

US3422280
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '31 Mar 2021'	Cindy Trimmer (b) (4) (b) (4)	31 Mar 2021 15:40:49

FDA-CBER-2022-1614-0805894

US3422280
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Clinic (Clinic)'	Cindy Trimmer (b) (4) (b) (4)	31 Mar 2021 15:40:49

US3422280
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User entered 'VISIT4'	System	31 Mar 2021 15:40:49

FDA-CBER-2022-1614-0805896

US3422280
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	31 Mar 2021 15:41:00

US3422280
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	31 Mar 2021 15:41:00

US3422280
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	31 Mar 2021 15:41:00

US3422280
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User entered empty.	System	31 Mar 2021 15:41:00

US3422280
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	31 Mar 2021 15:41:00

US3422280
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	31 Mar 2021 15:41:00

US3422280
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	31 Mar 2021 15:41:00

US3422280
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	31 Mar 2021 15:41:00

US3422280
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User entered empty.	System	31 Mar 2021 15:41:00

US3422280
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	31 Mar 2021 15:41:00

US3422280
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User entered empty.	System	31 Mar 2021 15:41:00

US3422280
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	31 Mar 2021 15:41:00

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US3422280
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User entered empty.	System	31 Mar 2021 15:41:00

US3422280
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	31 Mar 2021 15:41:00

US3422280
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User entered empty.	System	31 Mar 2021 15:41:00

US3422280
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30

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US3422280
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:40:19
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30

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US3422280
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:40:19
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	31 Mar 2021 15:41:05

US3422280
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:40:19
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	31 Mar 2021 15:41:05

US3422280
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:40:19
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	31 Mar 2021 15:41:14

US3422280
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:40:19
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '31 Mar 2021'	Cindy Trimmer (b) (4) (b) (4)	31 Mar 2021 15:41:14

US3422280
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:40:19
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '08:25'	Cindy Trimmer (b) (4) (b) (4)	31 Mar 2021 15:41:14

US3422280
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:40:19
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User entered '31 Mar 2021 08:25'	System	31 Mar 2021 15:41:14

US3422280
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	31 Mar 2021 15:41:20

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US3422280
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:40:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:58:30
User entered '1'	System	31 Mar 2021 15:41:20

FDA-CBER-2022-1614-0805921

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	14 Jan 2021 18:52:17

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '14 Jan 2021'	Cindy Trimmer (b) (4) (b) (4)	14 Jan 2021 18:52:17

FDA-CBER-2022-1614-0805923

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Clinic (Clinic)'	Cindy Trimmer (b) (4) (b) (4)	14 Jan 2021 18:52:17

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:40:19
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 18:52:17

FDA-CBER-2022-1614-0805925

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:40:19
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '06 Jan 2021'	Cindy Trimmer (b) (4) (b) (4)	14 Jan 2021 18:52:37

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:40:19
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 15:30:02
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:26:09

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:40:19
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	14 Jan 2021 18:52:37

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US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:40:19
Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	14 Apr 2021 19:27:23
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 11:38:10
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 02:42:34
Signature has been broken.		09 Apr 2021 02:42:14
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error		09 Apr 2021 02:42:14
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).		08 Apr 2021 19:16:13
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:30:02
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:26:09

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:40:19
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '14 Jan 2021'	Cindy Trimmer (b) (4) (b) (4)	14 Jan 2021 18:52:37

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:40:19
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'mRNA-1273 (mRNA-1273)'	Cindy Trimmer (b) (4) (b) (4)	14 Jan 2021 18:52:37

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:40:19
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 15:01:50
User entered 'mRNA-1273 (mRNA-1273)'	Cindy Trimmer (b) (4) (b) (4)	14 Jan 2021 18:52:37

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:40:19
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 15:01:50
User entered 'mRNA-1273 (mRNA-1273)'	Cindy Trimmer (b) (4) (b) (4)	14 Jan 2021 18:52:37

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:40:19
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	14 Jan 2021 18:52:37

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:40:19
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered empty.	System	14 Jan 2021 18:52:37

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US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:40:19
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered empty.	System	14 Jan 2021 18:52:37

FDA-CBER-2022-1614-0805936

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:40:19
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	14 Jan 2021 18:52:58

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:40:19
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '14 Jan 2021'	Cindy Trimmer (b) (4) (b) (4)	14 Jan 2021 18:52:58

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:40:19
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '10:59'	Cindy Trimmer (b) (4) (b) (4)	14 Jan 2021 18:52:58

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US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:40:19
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered '14 Jan 2021 10:59'	System	14 Jan 2021 18:52:58

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US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 11 Aug 2021 22:40:19
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	14 Jan 2021 18:53:22

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 11 Aug 2021 22:40:19
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '14 Jan 2021'	Cindy Trimmer (b) (4) (b) (4)	14 Jan 2021 18:53:22

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 11 Aug 2021 22:40:19
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '10:57'	Cindy Trimmer (b) (4) (b) (4)	14 Jan 2021 18:53:22

US3422280
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 11 Aug 2021 22:40:19
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:14
User entered '14 Jan 2021 10:57'	System	14 Jan 2021 18:53:22

US3422280
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 11 Aug 2021 22:40:19
Did the participant experience any adverse events?

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	22 Mar 2021 18:45:14

US3422280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:40:19

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:08:57
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User closed query 'Per DM CLR: Per Diary Dose 2 Day 1-3, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity/Repeated use of over-the-counter pain reliever , however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 07:52:34
Query 'Per DM CLR: Per Diary Dose 2 Day 1-3, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity/Repeated use of over-the-counter pain reliever , however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'UPDATED' (Site from DM).	April Hanlotxomphou (b) (4)	10 Mar 2021 19:47:24
User opened query 'Per DM CLR: Per Diary Dose 2 Day 1-3, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity/Repeated use of over-the-counter pain reliever , however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 00:01:46
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:39:45

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:40:19
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORETHISTERONE ACETATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 04:52:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 04:52:46
Data point term sent to Coder	System	15 Sep 2020 18:55:23
User entered 'NORETHINDRONE ac-eth estradiol' reason for change: Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:55:17
Data point term sent to Coder	System	15 Sep 2020 18:43:44
User entered 'Norethindrone'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:42:44

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US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:40:19
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:19:40
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'UPDATED' (Site from DM).	April Hanlotxomphou (b) (4)	04 Dec 2020 18:21:36
User entered 'Yes (Y)' reason for change: Data Entry Error	April Hanlotxomphou (b) (4)	04 Dec 2020 18:21:30
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 06:22:30
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:42:44

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:40:19
Indication

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'birth control'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:42:44

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:40:19
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 18:55:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 18:55:17
User entered '1/20' reason for change: Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:55:17
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 18:42:44
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:42:44

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:40:19
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 18:55:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 18:55:17
User entered 'Other (OTHER)' reason for change: Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:55:17
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 18:42:44
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:42:44

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:40:19
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'mg/mcg' reason for change: Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:55:17
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:42:44

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:40:19
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 18:55:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 18:55:17
User entered 'once daily (QD)' reason for change: Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:55:17
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 18:42:44
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:42:44

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:40:19
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:42:44

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:40:19
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 18:55:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 18:55:17
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:55:17
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 18:42:44
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:42:44

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:40:19
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:42:44

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:40:19
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'un UNK 2012' reason for change: New Information	(b) (4), (b) (6)	16 Oct 2020 17:57:45
User entered '30 Jun 2012'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:42:44

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:40:19
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:42:44

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:40:19
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:42:44

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:40:19
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:42:44

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:40:19
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:42:44

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US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:40:19
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 18:55:17
User entered empty.	System	15 Sep 2020 18:42:44

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:40:19
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 18:55:17
User entered empty.	System	15 Sep 2020 18:42:44

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:40:19
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 18:55:17
User entered empty.	System	15 Sep 2020 18:42:44

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:40:19
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 18:44:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 18:44:51
Data point term sent to Coder	System	15 Sep 2020 18:43:46
User entered 'Allegra'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:43:26

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:40:19
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:43:26

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US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:40:19
Indication

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Allergic rhinits'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:43:26

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:40:19
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '180'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:43:26

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:40:19
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'mg (mg)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:43:26

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:40:19
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:43:26

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:40:19
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'once daily (QD)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:43:26

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US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:40:19
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:43:26

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:40:19
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:43:26

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:40:19
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:43:26

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:40:19
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'un UNK 2018' reason for change: New Information	(b) (4), (b) (6)	16 Oct 2020 17:58:10
User entered '30 Jun 2018'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:43:26

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US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:40:19
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:43:26

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:40:19
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:43:26

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:40:19
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:43:26

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:40:19
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:43:26

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:40:19
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 18:43:26

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:40:19
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 18:43:26

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:40:19
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 18:43:26

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:40:19
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: RETINOIDS FOR TOPICAL USE IN ACNE, PRODUCT: TRETINOIN, PRODUCTSYNONYM: RETIN-A - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 18:46:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 18:46:56
Data point term sent to Coder	System	15 Sep 2020 18:45:52
User entered 'Retin-A'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:45:34

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:40:19
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:45:34

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:40:19
Indication

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'acne'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:45:34

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:40:19
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '1' reason for change: Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:47:38
User entered '0.025 %'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:45:34

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:40:19
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Other (OTHER)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:45:34

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:40:19
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	15 Sep 2020 18:47:38
User entered 'application' reason for change: Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:47:38
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	15 Sep 2020 18:45:34
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:45:34

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:40:19
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'once daily (QD)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:45:34

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:40:19
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:45:34

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:40:19
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Topical (TOPICAL)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:45:34

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:40:19
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:45:34

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:40:19
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'un UNK 2020' reason for change: New Information	(b) (4), (b) (6)	16 Oct 2020 17:58:38
User entered '30 Jan 2020'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:45:34

FDA-CBER-2022-1614-0805993

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:40:19
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:45:34

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:40:19
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:45:34

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:40:19
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:45:34

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:40:19
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:45:34

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:40:19
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 18:45:34

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:40:19
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 18:45:34

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:40:19
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 18:45:34

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:40:19
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:39
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:51:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:51:54
Data point term sent to Coder	System	10 Mar 2021 19:47:34
Coding entries removed.	April Hanlotxomphou (b) (4)	10 Mar 2021 19:47:14
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 13:40:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 13:40:36
Data point term sent to Coder	System	26 Oct 2020 13:39:40
User entered 'Ibuprofen'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:39:35

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:40:19
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:39
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:39:35

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:40:19
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:39
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE/BODY ACHES/PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE/BODY ACHES/PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 11:40:24
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE/BODY ACHES/PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE/BODY ACHES/PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' answered with 'does not meet AE reporting criteria, happened during 7 day solicited event period following vaccine' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 14:21:43

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:40:19
Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE/BODY ACHES/PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE/BODY ACHES/PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:21:36
User entered 'HEADACHE/BODY ACHES/PAIN AT INJECTION SITE' reason for change: Data Entry Error	April Hanlotxomphou (b) (4)	10 Mar 2021 19:47:14
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE/BODY ACHES are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE/BODY ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 07:35:49

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:40:19
Indication

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE/BODY ACHES are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE/BODY ACHES did not meet the AE reporting criteria.' answered with 'AE NOT NECESSARY AS SYMPTOM OCCURRED DURING 7 DAY SOLICITED EVENT PERIOD POST INJECTION.' (Site from DM).	April Hanlotxomphou (b) (4)	22 Dec 2020 18:48:12
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE/BODY ACHES are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE/BODY ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 08:06:22
User entered 'Headache/Body aches'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:39:35

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:40:19
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:39
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '800'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:39:35

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:40:19
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:39
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'mg (mg)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:39:35

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:40:19
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:39
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:39:35

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:40:19
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:39
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'as needed (PRN)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:39:35

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:40:19
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:39
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:39:35

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:40:19
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:39
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:39:35

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:40:19
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:39
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:39:35

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:40:19
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:39
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User closed query 'Per DM CLR: Please review Start date of this medication as this is before the occurrence of Headache/body aches which started 17 Oct 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 07:35:18
Query 'Per DM CLR: Please review Start date of this medication as this is before the occurrence of Headache/body aches which started 17 Oct 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.' answered with 'UPDATED' (Site from DM).	April Hanlotxomphou (b) (4)	22 Dec 2020 18:47:39
User entered '17 Oct 2020' reason for change: Data Entry Error	April Hanlotxomphou (b) (4)	22 Dec 2020 18:47:19
User opened query 'Per DM CLR: Please review Start date of this medication as this is before the occurrence of Headache/body aches which started 17 Oct 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 08:06:59
User entered '16 Oct 2020'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:39:35

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:40:19
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:39
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:39:35

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:40:19
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:39
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:39:35

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:40:19
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:39
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '19 Oct 2020' reason for change: Data Entry Error	April Hanlotxomphou (b) (4)	10 Mar 2021 19:47:14
User entered '18 Oct 2020'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:39:35

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:40:19
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:39
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	26 Oct 2020 13:39:35

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US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:40:19
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:39
User entered empty.	System	26 Oct 2020 13:39:35

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:40:19
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:39
User entered empty.	System	26 Oct 2020 13:39:35

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:40:19
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:39
User entered empty.	System	26 Oct 2020 13:39:35

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:40:19
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
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)	16 Nov 2020 16:09:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 16:09:46
Data point term sent to Coder	System	16 Nov 2020 16:08:04
User entered 'influenza vaccine'	(b) (4), (b) (6)	16 Nov 2020 16:07:54

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:40:19
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 16:07:54

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:40:19
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'health maintenance'	(b) (4), (b) (6)	16 Nov 2020 16:07:54

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:40:19
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '0.5'	(b) (4), (b) (6)	16 Nov 2020 16:07:54

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:40:19
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'mL (mL)'	(b) (4), (b) (6)	16 Nov 2020 16:07:54

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:40:19
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 16:07:54

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:40:19
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	16 Nov 2020 20:57:28
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	16 Nov 2020 20:57:28
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	16 Nov 2020 16:09:03
User entered 'once (ONCE)'	(b) (4), (b) (6)	16 Nov 2020 16:07:54

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:40:19
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 16:07:54

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:40:19
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	16 Nov 2020 16:07:54

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:40:19
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 16:07:54

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:40:19
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Nov 2020 16:09:03
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 16:09:03
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Nov 2020 16:07:54
User entered '1 ' (non-conformant).	(b) (4), (b) (6)	16 Nov 2020 16:07:54

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:40:19
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 16:07:54

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:40:19
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 16:09:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 16:09:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 16:09:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 16:07:54
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 16:07:54

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:40:19
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered '13 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	16 Nov 2020 20:57:28
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 16:09:03
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 16:07:54

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:40:19
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:54
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 16:09:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 16:09:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 16:09:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 16:07:54
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 16:07:54

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:40:19
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:54
User entered empty.	System	16 Nov 2020 16:07:54

US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:40:19
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:54
User entered empty.	System	16 Nov 2020 16:07:54

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US3422280
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:40:19
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:45:54
User entered empty.	System	16 Nov 2020 16:07:54

US3422280
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 11 Aug 2021 22:40:19
Were any concomitant procedures performed?

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:28:58
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	24 Mar 2021 18:04:05