US3142056 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

Generated By: KC Joubran

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US3142056
Form: Participant Creation
Data signed: (b) (4) **18 Apr 2021 19:13:25**
Generated On: 11 Aug 2021 22:00:27

Participant ID	US3142056

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-0081857

US3142056
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0081858

US3142056
Folder: Screening
Form: Demographics
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	58
Age Units	YEARS
Age (Derived)	58
Sex	Female ☐
	Male ■
Ethnicity	Hispanic or Latino ☐
	Not Hispanic or Latino ■
	Not Reported ☐
	Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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US3142056
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Date of Informed Consent *(dd MMM yyyy)*	03 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐ Amendment 2 ■ Amendment 3 ☐ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ■ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ■
If Yes, previous participant number	
Enrollment Trigger	1

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US3142056
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

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

US3142056
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Were any significant conditions reported?	Yes ■ No ☐

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US3142056
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

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

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US3142056
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1974
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 1974
Start Year (derived)	1974
Stop Month and Year (derived)	
Stop Year (derived)	

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US3142056
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

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

US3142056
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

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

US3142056
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **18 Apr 2021 19:13:51**
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Condition	RIGHT HERNIA INGUINAL
Start date (dd MMM yyyy)	UN UNK 1984
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1984
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	JAN 1984
Stop Year (derived)	1984

US3142056
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Condition	HEADACHES
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	
Stop Year (derived)	

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US3142056
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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US3142056
Folder: Screening
Form: Medical History (8)
Data signed: (b) (4) **18 Apr 2021 19:13:51**
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Condition	GERD
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0081870

US3142056
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	03 AUG 2020
Time of assessment *(00:00-23:59)*	08:55 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 08:55
Height *(xxx.x)*	74 in
Weight *(xxx.x)*	249 lb
BMI *(xxx.x)*	32.03655 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)	

US3142056
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **18 Apr 2021 19:13:51**
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Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	03 AUG 2020

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

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US3142056
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **18 Apr 2021 19:13:51**
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Occupational Risk	
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☐ No ■
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐ No ■
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐ No ■
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐ No ■
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐ No ■
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ■ No ☐
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐ No ■
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐ No ■
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐ No ■
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐ No ■
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐ No ■
Other	Yes ☐ No ■
Specify	
Location and Living Circumstances Risk (check all that apply)	
No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False

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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	

US3142056
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

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

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US3142056
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **18 Apr 2021 19:13:51**
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What was the date of randomization? *(dd MMM yyyy)*	03 AUG 2020
What was the participant's randomization number?	142604
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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US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **18 Apr 2021 19:13:51**
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Height	ND - Not Done
Weight	ND - Not Done

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US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

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)*	03 AUG 2020
Time of assessment *(00:00-23:59)*	08:55 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 08:55
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	57 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	73 mmHg
Diastolic Blood Pressure units	MMHG

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

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)*	03 AUG 2020
Time of assessment *(00:00-23:59)*	10:51 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 10:51
Temperature *(xxx.x)*	97.7 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	56 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	96 mmHg
Diastolic Blood Pressure units	MMHG

US3142056
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

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

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

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US3142056
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	3 AUG 2020
What was the treatment time? *(00:00-23:59)*	10:19 (24 HR)
Treatment Date and Time (derived)	3 AUG 2020 10:19
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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US3142056
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	03 AUG 2020
Collection time *(00:00-23:59)*	10:03 (24 HR)
Collection date and time (derived)	03 AUG 2020 10:03

FDA-CBER-2022-1614-0081882

US3142056
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Collection date *(dd MMM yyyy)*			03 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:03	03 AUG 2020 10:03
Nasopharyngeal Swab 2	Yes	10:03	03 AUG 2020 10:03

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US3142056
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0081884

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:00:27

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.6 °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	03 AUG 2020 10:53
PC Open Date & Time	03 AUG 2020 10:39
PC Close Date & Time	03 AUG 2020 13:09

FDA-CBER-2022-1614-0081885

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:00:27

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**	96.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	03 AUG 2020 20:17
PC Open Date & Time	03 AUG 2020 14:04
PC Close Date & Time	04 AUG 2020 11:59

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US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:00:27

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**	96.7 °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	04 AUG 2020 21:52
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:00:27

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**	95.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	05 AUG 2020 21:53
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

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US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:00:27

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**	95.4 °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	06 AUG 2020 21:30
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

FDA-CBER-2022-1614-0081889

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:00:27

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.9 °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	08 AUG 2020 01:29
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

FDA-CBER-2022-1614-0081890

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:00:27

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**	97.0 °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	09 AUG 2020 00:49
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:00:27

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	96.0 °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	10 AUG 2020 00:20
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:00:27

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	03 AUG 2020 10:54
PC Open Date & Time	03 AUG 2020 10:39
PC Close Date & Time	03 AUG 2020 13:09

FDA-CBER-2022-1614-0081893

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:00:27

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	03 AUG 2020 20:18
PC Open Date & Time	03 AUG 2020 14:04
PC Close Date & Time	04 AUG 2020 11:59

FDA-CBER-2022-1614-0081894

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:00:27

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	04 AUG 2020 21:53
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

FDA-CBER-2022-1614-0081895

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:00:27

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	05 AUG 2020 21:54
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

FDA-CBER-2022-1614-0081896

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:00:27

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	06 AUG 2020 21:31
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

FDA-CBER-2022-1614-0081897

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:00:27

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	08 AUG 2020 01:29
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:00:27

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	09 AUG 2020 00:49
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

FDA-CBER-2022-1614-0081899

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:00:27

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	10 AUG 2020 00:20
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 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-2022-1614-0081901

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	03 AUG 2020 10:54
PC Open Date & Time	03 AUG 2020 10:39
PC Close Date & Time	03 AUG 2020 13:09

FDA-CBER-2022-1614-0081902

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-2022-1614-0081903

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	03 AUG 2020 20:18
PC Open Date & Time	03 AUG 2020 14:04
PC Close Date & Time	04 AUG 2020 11:59

FDA-CBER-2022-1614-0081904

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27

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-2022-1614-0081905

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27

	Yes ☐
PC Time stamp	04 AUG 2020 21:53
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

FDA-CBER-2022-1614-0081906

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27

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-2022-1614-0081907

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27

	Yes ☐
PC Time stamp	05 AUG 2020 21:55
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

FDA-CBER-2022-1614-0081908

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27

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-2022-1614-0081909

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27

	Yes ☐
PC Time stamp	06 AUG 2020 21:31
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27

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 ■

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27

	Yes ☐
PC Time stamp	08 AUG 2020 01:30
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

FDA-CBER-2022-1614-0081912

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27

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-2022-1614-0081913

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27

	Yes ☐
PC Time stamp	09 AUG 2020 00:49
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

FDA-CBER-2022-1614-0081914

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27

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-2022-1614-0081915

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27

	Yes ☐
PC Time stamp	10 AUG 2020 00:21
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3142056
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0081917

US3142056
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0081918

US3142056
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	17 AUG 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-0081919

US3142056
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

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

US3142056
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	24 AUG 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0081921

US3142056
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0081922

US3142056
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	1 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-0081923

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	1 SEP 2020
Time of assessment *(00:00-23:59)*	07:58 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 07:58
Temperature *(xxx.x)*	97.3 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	63 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	84 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0081924

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	1 SEP 2020
Time of assessment *(00:00-23:59)*	08:53 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 08:53
Temperature *(xxx.x)*	96.6 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	59 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0081925

US3142056
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	1 SEP 2020

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

FDA-CBER-2022-1614-0081926

US3142056
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

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)*	1 SEP 2020
What was the treatment time? *(00:00-23:59)*	14:45 (24 HR)
Treatment Date and Time (derived)	1 SEP 2020 14:45
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

US3142056
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	1 SEP 2020
Collection time *(00:00-23:59)*	08:06 (24 HR)
Collection date and time (derived)	1 SEP 2020 08:06

US3142056
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Collection date *(dd MMM yyyy)* 1 SEP 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:07	1 SEP 2020 08:07
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0081929

US3142056
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0081930

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:00:27

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**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	01 SEP 2020 15:05
PC Close Date & Time	01 SEP 2020 17:35

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:00:27

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**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	01 SEP 2020 18:30
PC Close Date & Time	02 SEP 2020 11:59

FDA-CBER-2022-1614-0081932

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:00:27

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☐ No ☐
Please record your **TEMPERATURE in °F**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

FDA-CBER-2022-1614-0081933

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:00:27

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**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-0081934

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:00:27

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**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

FDA-CBER-2022-1614-0081935

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:00:27

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**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-0081936

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:00:27

TIMEPOINT	DAY 6

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

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

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

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

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

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

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

FDA-CBER-2022-1614-0081937

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:00:27

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**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-0081938

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 ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	01 SEP 2020 15:05
PC Close Date & Time	01 SEP 2020 17:35

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:00:27

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 ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	01 SEP 2020 18:30
PC Close Date & Time	02 SEP 2020 11:59

FDA-CBER-2022-1614-0081940

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:00:27

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

FDA-CBER-2022-1614-0081941

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:00:27

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.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-0081942

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:00:27

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.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:00:27

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.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:00:27

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

FDA-CBER-2022-1614-0081945

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:00:27

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 ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-0081946

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-2022-1614-0081947

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	01 SEP 2020 15:05
PC Close Date & Time	01 SEP 2020 17:35

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-2022-1614-0081949

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	01 SEP 2020 18:30
PC Close Date & Time	02 SEP 2020 11:59

FDA-CBER-2022-1614-0081950

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27

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-2022-1614-0081951

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0081952

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27

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-2022-1614-0081953

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0081954

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 ☐

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0081956

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27

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-2022-1614-0081957

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

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-2022-1614-0081959

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27

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

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27

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-2022-1614-0081961

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0081962

US3142056
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	8 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-2022-1614-0081963

US3142056
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

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

US3142056
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	17 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-2022-1614-0081965

US3142056
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0081966

US3142056
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

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-2022-1614-0081967

US3142056
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0081968

US3142056
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-0081969

US3142056
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	29 SEP 2020
Time of assessment *(00:00-23:59)*	08:18 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 08:18
Temperature *(xxx.x)*	96.2 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	61 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142056
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	29 SEP 2020

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

FDA-CBER-2022-1614-0081971

US3142056
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	29 SEP 2020
Collection time *(00:00-23:59)*	08:25 (24 HR)
Collection date and time (derived)	29 SEP 2020 08:25

FDA-CBER-2022-1614-0081972

US3142056
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **26 Apr 2021 02:38:56**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0081973

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have 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-2022-1614-0081974

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	03 OCT 2020 00:01
Patient Cloud Close Date & Time	07 OCT 2020 23:59

FDA-CBER-2022-1614-0081975

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

FDA-CBER-2022-1614-0081977

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 OCT 2020 01:34:36
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

FDA-CBER-2022-1614-0081978

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 OCT 2020 00:02:33
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

FDA-CBER-2022-1614-0081979

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-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	09 NOV 2020 02:55:24
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

FDA-CBER-2022-1614-0081980

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Date and time of submission	15 NOV 2020 01:11:08
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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	20 NOV 2020 13:54:51
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

FDA-CBER-2022-1614-0081982

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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	25 NOV 2020 05:46:29
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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	05 DEC 2020 09:20:27
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Date and time of submission	18 DEC 2020 07:02:39
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Date and time of submission	23 DEC 2020 06:41:21
Patient Cloud Open Date & Time	23 DEC 2020 00:01

Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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	30 DEC 2020 09:33:24
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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	09 JAN 2021 07:43:39
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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	16 JAN 2021 04:42:54
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Date and time of submission	31 JAN 2021 16:51:45
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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	06 FEB 2021 00:49:25
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

FDA-CBER-2022-1614-0081996

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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	19 FEB 2021 04:33:03
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

FDA-CBER-2022-1614-0081999

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 FEB 2021 00:37:15
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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	03 MAR 2021 01:11:24
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

FDA-CBER-2022-1614-0082001

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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	10 MAR 2021 23:51:53
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 MAR 2021 04:26:23
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 MAR 2021 01:25:39
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

FDA-CBER-2022-1614-0082004

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 MAR 2021 10:27:58
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 APR 2021 09:29:02
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

FDA-CBER-2022-1614-0082006

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 APR 2021 07:16:58
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 APR 2021 06:39:20
Patient Cloud Open Date & Time	21 APR 2021 00:01
Patient Cloud Close Date & Time	25 APR 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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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 ☐

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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 ☐

FDA-CBER-2022-1614-0082023

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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 ☐

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

FDA-CBER-2022-1614-0082046

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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 ☐

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082054

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082056

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082058

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082060

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

FDA-CBER-2022-1614-0082062

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082064

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082066

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082074

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082076

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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 ☐

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Folder: New Safety Follow Up Diary (1)
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Generated On: 11 Aug 2021 22:00:27

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

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 ☐

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

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 ☐

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

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

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

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

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 ☐

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

TIMEPOINT	DAY 565
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

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

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 ☐

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

FDA-CBER-2022-1614-0082098

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 ☐

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Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

US3142056
Folder: New Safety Follow Up Diary (1)
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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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
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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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082112

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082114

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	11 MAY 2022 00:01
Patient Cloud Close Date & Time	15 MAY 2022 23:59

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082122

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
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Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	08 JUN 2022 00:01
Patient Cloud Close Date & Time	12 JUN 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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	15 JUN 2022 00:01
Patient Cloud Close Date & Time	19 JUN 2022 23:59

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082143

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082146

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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 ☐

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082152

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0082157

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082158

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 ☐

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082160

US3142056
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 11 Aug 2021 22:00:27

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		28 FEB 2021 01:11:14

US3142056
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	27 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-2022-1614-0082162

US3142056
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082163

US3142056
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	30 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-2022-1614-0082164

US3142056
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082165

US3142056
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **26 Apr 2021 02:38:56**
Generated On: 11 Aug 2021 22:00:27

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	6 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-2022-1614-0082166

US3142056
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082167

US3142056
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **26 Apr 2021 02:38:56**
Generated On: 11 Aug 2021 22:00:27

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	26 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-2022-1614-0082168

US3142056
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082169

US3142056
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	01 APR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT4

FDA-CBER-2022-1614-0082170

US3142056
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

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)	

US3142056
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

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.

US3142056
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	01 APR 2021
Collection time *(00:00-23:59)*	08:20 (24 HR)
Collection date and time (derived)	01 APR 2021 08:20

FDA-CBER-2022-1614-0082173

US3142056
Folder: Visit 4 Day 209 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082174

US3142056
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082175

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

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: COVID-19 Contact
Data signed: (b) (4) **26 Apr 2021 02:38:55**
Generated On: 11 Aug 2021 22:00:27

Date of Contact	11 NOV 2020
Time of Contact	09:00
Date and Time of Contact (derived)	11 NOV 2020 09:00
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-2022-1614-0082177

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Data signed: (b) (4) **03 May 2021 15:03:31**
Generated On: 11 Aug 2021 22:00:27

Symptom Day

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

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	09 NOV 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Data signed: (b) (4) **03 May 2021 15:03:31**
Generated On: 11 Aug 2021 22:00:27

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

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

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Data signed: (b) (4) **03 May 2021 15:03:31**
Generated On: 11 Aug 2021 22:00:27

Symptom Day

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

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	10 NOV 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Data signed: (b) (4) **03 May 2021 15:03:31**
Generated On: 11 Aug 2021 22:00:27

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

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

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Data signed: (b) (4) **03 May 2021 15:03:31**
Generated On: 11 Aug 2021 22:00:27

Symptom Day

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

FDA-CBER-2022-1614-0082186

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	11 NOV 2020
Assessment Not Done	True
O2 Saturation	92 %
O2 Saturation Units	%
Temperature	98.5 F
Chills	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Data signed: (b) (4) **03 May 2021 15:03:31**
Generated On: 11 Aug 2021 22:00:27

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

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

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Data signed: (b) (4) **03 May 2021 15:03:31**
Generated On: 11 Aug 2021 22:00:27

Symptom Day

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

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	12 NOV 2020
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	98.0 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

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

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

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Data signed: (b) (4) **03 May 2021 15:03:31**
Generated On: 11 Aug 2021 22:00:27

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [x] Day 5
- [ ] Day 6
- [ ] Day 7
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- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [ ] Day 19
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- [ ] Day 32

FDA-CBER-2022-1614-0082194

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	13 NOV 2020
Assessment Not Done	False
O2 Saturation	95 %
O2 Saturation Units	%
Temperature	97.2 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Data signed: (b) (4) **03 May 2021 15:03:31**
Generated On: 11 Aug 2021 22:00:27

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

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

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: COVID Diagnostic Test
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Date of Visit	11 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ■ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☐ No ■
Date of Test	11 NOV 2020
Type of Test Performed	Nasopharyngeal Swab ■ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ■
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	0

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Generate Next COVID-19 Assessment
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Generate Next COVID-19 Assessment	Yes ■ No ☐

FDA-CBER-2022-1614-0082199

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: COVID-19 Contact
Data signed: (b) (4) **26 Apr 2021 02:38:55**
Generated On: 11 Aug 2021 22:00:27

Date of Contact	21 DEC 2020
Time of Contact	09:00
Date and Time of Contact (derived)	21 DEC 2020 09:00
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 ☐

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Data signed: (b) (4) **03 May 2021 15:03:32**
Generated On: 11 Aug 2021 22:00:27

Symptom Day

- [x] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
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- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [ ] Day 19
- [ ] Day 20
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- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-0082201

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	17 DEC 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

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

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

Symptom Day

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

FDA-CBER-2022-1614-0082205

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	18 DEC 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Shortness of Breath	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Data signed: (b) (4) **03 May 2021 15:03:32**
Generated On: 11 Aug 2021 22:00:27

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

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

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Data signed: (b) (4) **03 May 2021 15:03:32**
Generated On: 11 Aug 2021 22:00:27

Symptom Day

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

FDA-CBER-2022-1614-0082209

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	19 DEC 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Data signed: (b) (4) **03 May 2021 15:03:32**
Generated On: 11 Aug 2021 22:00:27

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

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

FDA-CBER-2022-1614-0082212

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Data signed: (b) (4) **03 May 2021 15:03:32**
Generated On: 11 Aug 2021 22:00:27

Symptom Day

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

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	20 DEC 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Data signed: (b) (4) **03 May 2021 15:03:32**
Generated On: 11 Aug 2021 22:00:27

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

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

FDA-CBER-2022-1614-0082216

Symptom Day

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

FDA-CBER-2022-1614-0082217

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	21 DEC 2020
Assessment Not Done	False
O2 Saturation	91 %
O2 Saturation Units	%
Temperature	97.5 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Data signed: (b) (4) **03 May 2021 15:03:32**
Generated On: 11 Aug 2021 22:00:27

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

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

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Data signed: (b) (4) **03 May 2021 15:03:32**
Generated On: 11 Aug 2021 22:00:27

Symptom Day

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

FDA-CBER-2022-1614-0082221

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	22 DEC 2020
Assessment Not Done	False
O2 Saturation	94 %
O2 Saturation Units	%
Temperature	97.0 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Data signed: (b) (4) **03 May 2021 15:03:32**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082223

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

Symptom Day

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

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	23 DEC 2020
Assessment Not Done	False
O2 Saturation	94 %
O2 Saturation Units	%
Temperature	97.1 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Data signed: (b) (4) **03 May 2021 15:03:32**
Generated On: 11 Aug 2021 22:00:27

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

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

Symptom Day

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

FDA-CBER-2022-1614-0082229

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	24 DEC 2020
Assessment Not Done	False
O2 Saturation	94 %
O2 Saturation Units	%
Temperature	97.4 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Data signed: (b) (4) **03 May 2021 15:03:32**
Generated On: 11 Aug 2021 22:00:27

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

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

Symptom Day

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

FDA-CBER-2022-1614-0082233

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	25 DEC 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Data signed: (b) (4) **03 May 2021 15:03:32**
Generated On: 11 Aug 2021 22:00:27

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

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

Symptom Day

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

FDA-CBER-2022-1614-0082237

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	26 DEC 2020
Assessment Not Done	False
O2 Saturation	94 %
O2 Saturation Units	%
Temperature	97.1 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

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

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

Symptom Day

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

FDA-CBER-2022-1614-0082241

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	27 DEC 2020
Assessment Not Done	False
O2 Saturation	95 %
O2 Saturation Units	%
Temperature	97.4 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

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

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

Symptom Day

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

FDA-CBER-2022-1614-0082245

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	28 DEC 2020
Assessment Not Done	False
O2 Saturation	95 %
O2 Saturation Units	%
Temperature	96.6 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Data signed: (b) (4) **03 May 2021 15:03:32**
Generated On: 11 Aug 2021 22:00:27

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

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

Symptom Day

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

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	29 DEC 2020
Assessment Not Done	False
O2 Saturation	95 %
O2 Saturation Units	%
Temperature	96.4 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Data signed: (b) (4) **03 May 2021 15:03:32**
Generated On: 11 Aug 2021 22:00:27

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

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

Symptom Day

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

FDA-CBER-2022-1614-0082253

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	30 DEC 2020
Assessment Not Done	False
O2 Saturation	94 %
O2 Saturation Units	%
Temperature	96.5 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

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

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

Symptom Day

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

FDA-CBER-2022-1614-0082257

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	31 DEC 2020
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	96.9 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

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

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

Symptom Day

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

FDA-CBER-2022-1614-0082261

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	01 JAN 2021
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	97.0 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

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

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

Symptom Day

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

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	02 JAN 2021
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	96.1 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Data signed: (b) (4) **03 May 2021 15:03:32**
Generated On: 11 Aug 2021 22:00:27

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

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

Symptom Day

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

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	03 JAN 2021
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	97.2 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

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

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

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
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- [ ] Day 18
- [ ] Day 19
- [ ] Day 20
- [ ] Day 21
- [x] Day 22
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- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-0082273

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	10 JAN 2021
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	96.3 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Data signed: (b) (4) **03 May 2021 15:03:32**
Generated On: 11 Aug 2021 22:00:27

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

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

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: COVID Diagnostic Test
Data signed: (b) (4) **26 Apr 2021 02:38:55**
Generated On: 11 Aug 2021 22:00:27

Date of Visit	21 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ■ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ■ No ☐
Date of Test	21 DEC 2020
Type of Test Performed	Nasopharyngeal Swab ■ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ■
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	1

FDA-CBER-2022-1614-0082277

Did the subject have Respiratory Rates ≥ 30 per Minute?	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
Respiratory Rate	
Did the subject have Heart Rate ≥ 125 beats per minute	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
Heart Rate	
Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?	Yes ■ No ☐
If Yes, provide:	
Start Date	21 DEC 2020
End Date	21 DEC 2020
Oxygen Saturation	91 %
Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
PaO2	

Did the subject have Respiratory failure?	Yes ☐ No ■
Start Date	
Did the subject have Acute Respiratory Distress Syndrome (ARDS)?	Yes ☐ No ■
Start Date	

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

Ventilator Support:	
High-Flow Oxygen?	Yes ☐ No ☒
Start Date	
End Date	
Non-Invasive Ventilation?	Yes ☐ No ☒
Start Date	
End Date	
Mechanical Ventilation?	Yes ☐ No ☒
Start Date	
End Date	
ECMO?	Yes ☐ No ☒
Start Date	
End Date	
Evidence of Shock:	
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg	Yes ☐ No ☒
Start Date	
End Date	
Evidence of Shock Requires Vasopressors	Yes ☐ No ☒
Start Date	
End Date	
Acute Renal Dysfunction?	Yes ☐ No ☒
Start Date	

Hepatic Dysfunction?	Yes ☐ No ■
Start Date	
Neurologic Dysfunction?	Yes ☐ No ■
Start Date	

Evidence of Pneumonia:

Clinical Evidence	Yes ☐ No ■
Date of Assessment	
Radiographical Evidence	Yes ☐ No ■
Date of Assessment	

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

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

FDA-CBER-2022-1614-0082281

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection
Data signed: (b) (4) **26 Apr 2021 02:38:56**
Generated On: 11 Aug 2021 22:00:27

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

FDA-CBER-2022-1614-0082282

US3142056
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	21 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SICKD1

FDA-CBER-2022-1614-0082283

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	21 DEC 2020
Time of assessment *(00:00-23:59)*	09:10 (24 HR)
Vital Signs Date and Time (derived)	21 DEC 2020 09:10
Height *(xxx.x)*	ND - Not Done
Weight *(xxx.x)*	ND - Not Done
Temperature *(xxx.x)*	97.5 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	84 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0082284

US3142056
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	21 DEC 2020

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

FDA-CBER-2022-1614-0082285

US3142056
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ■ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	21 DEC 2020

FDA-CBER-2022-1614-0082286

US3142056
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Data signed: (b) (4) **26 Apr 2021 02:38:56**
Generated On: 11 Aug 2021 22:00:27

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	11 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SICKD1

FDA-CBER-2022-1614-0082287

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Data signed: (b) (4) **26 Apr 2021 02:38:56**
Generated On: 11 Aug 2021 22:00:27

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	11 NOV 2020
Time of assessment *(00:00-23:59)*	09:12 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 09:12
Height *(xxx.x)*	ND - Not Done
Weight *(xxx.x)*	ND - Not Done
Temperature *(xxx.x)*	98.5 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	88 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0082288

US3142056
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Data signed: (b) (4) **26 Apr 2021 02:38:56**
Generated On: 11 Aug 2021 22:00:27

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	11 NOV 2020

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

US3142056
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **03 May 2021 15:03:34**
Generated On: 11 Aug 2021 22:00:27

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ☐ No ☐ NA (COVID-19 Negative) ■
Date of Collection	11 NOV 2020

FDA-CBER-2022-1614-0082290

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Data signed: (b) (4) **18 Apr 2021 19:13:25**
Generated On: 11 Aug 2021 22:00:27

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	28 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SICKD28

FDA-CBER-2022-1614-0082291

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Data signed: (b) (4) **26 Apr 2021 02:38:55**
Generated On: 11 Aug 2021 22:00:27

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	28 JAN 2021
Time of assessment *(00:00-23:59)*	08:00 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 08:00
Temperature *(xxx.x)*	97.0 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	72 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	98 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Data signed: (b) (4) **18 Apr 2021 19:13:25**
Generated On: 11 Aug 2021 22:00:27

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	28 JAN 2021

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

FDA-CBER-2022-1614-0082293

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **18 Apr 2021 19:13:25**
Generated On: 11 Aug 2021 22:00:27

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ■ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	28 JAN 2021

FDA-CBER-2022-1614-0082294

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Data signed: (b) (4) **26 Apr 2021 02:38:55**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082295

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Data signed: (b) (4) **26 Apr 2021 02:38:55**
Generated On: 11 Aug 2021 22:00:27

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)	

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Data signed: (b) (4) **26 Apr 2021 02:38:54**
Generated On: 11 Aug 2021 22:00:27

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.

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **26 Apr 2021 02:38:54**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082298

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	23 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	UNBLND_DECIDE

FDA-CBER-2022-1614-0082299

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Date of updated informed consent *(dd MMM yyyy)*	23 FEB 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)*	23 FEB 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	1
Continuing with mRNA-1273	1

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

FDA-CBER-2022-1614-0082301

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	23 FEB 2021
Time of assessment *(00:00-23:59)*	08:26 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 08:26
Temperature *(xxx.x)*	96.6 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	70 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	23 FEB 2021
Time of assessment *(00:00-23:59)*	09:42 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 09:42
Temperature *(xxx.x)*	97.5 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	65 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	92 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0082303

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	23 FEB 2021

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

FDA-CBER-2022-1614-0082304

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

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? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	23 FEB 2021
What was the treatment time? *(00:00-23:59)*	09:12 (24 HR)
Treatment Date and Time (derived)	23 FEB 2021 09:12
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-2022-1614-0082305

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	23 FEB 2021
Collection time *(00:00-23:59)*	08:17 (24 HR)
Collection date and time (derived)	23 FEB 2021 08:17

FDA-CBER-2022-1614-0082306

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	23 FEB 2021
Collection time *(00:00 - 23:59)*	08:18
Collection Date and Time (derived)	23 FEB 2021 08:18

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082308

US3142056
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	03 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-2022-1614-0082309

US3142056
Folder: Safety Call OL-D8 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 19:13:51**
Generated On: 11 Aug 2021 22:00:27

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1
OLD29 Placebo Flag	1

FDA-CBER-2022-1614-0082310

US3142056
Folder: OL-D29 (1)
Form: Visit Date
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	01 APR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	OLD29

FDA-CBER-2022-1614-0082311

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	01 APR 2021
Time of assessment *(00:00-23:59)*	08:29 (24 HR)
Vital Signs Date and Time (derived)	01 APR 2021 08:29
Temperature *(xxx.x)*	97.5 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	64 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	79 mmHg
Diastolic Blood Pressure units	MMHG

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	01 APR 2021
Time of assessment *(00:00-23:59)*	09:20 (24 HR)
Vital Signs Date and Time (derived)	01 APR 2021 09:20
Temperature *(xxx.x)*	97.3 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	57 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	81 mmHg
Diastolic Blood Pressure units	MMHG

US3142056
Folder: OL-D29 (1)
Form: Physical Examination
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	01 APR 2021

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

FDA-CBER-2022-1614-0082314

US3142056
Folder: OL-D29 (1)
Form: Exposure
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

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? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	01 APR 2021
What was the treatment time? *(00:00-23:59)*	08:49 (24 HR)
Treatment Date and Time (derived)	01 APR 2021 08:49
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-2022-1614-0082315

US3142056
Folder: OL-D29 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082316

US3142056
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082317

US3142056
Folder: Safety Call OL-D36 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082318

US3142056
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082319

US3142056
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27

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)	

US3142056
Folder: OL-D57 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27

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-2022-1614-0082321

Was the sample collected?	Yes ☐ No ☐
Collection date *(dd MMM yyyy)*	
Collection time *(00:00-23:59)*	
Collection date and time (derived)	

US3142056
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **26 Apr 2021 02:38:54**
Generated On: 11 Aug 2021 22:00:27

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

If Yes, enter details on the Adverse Events form.

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **26 Apr 2021 02:38:54**
Generated On: 11 Aug 2021 22:00:27

AEID	USA-US064-2021-MRNA-1273-P301000008
Adverse event	COVID-19
Was this a medically-attended AE?	Yes ■ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ■ No ☐
Start date *(dd MMM yyyy)*	21 DEC 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	4 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ■ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☐ Related ☐ Not Applicable ■
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	COUGH, SHORTNESS OF BREATH, DIFFICULTY BREATHING, FATIGUE, BODY AND MUSCLE ACHES, HEADACHE, SORE THROAT, RUNNY NOSE
Serious Adverse Event Derived (CSA Programming Field Ony)	0

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **26 Apr 2021 02:38:54**
Generated On: 11 Aug 2021 22:00:27

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

FDA-CBER-2022-1614-0082326

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **18 Apr 2021 19:13:25**
Generated On: 11 Aug 2021 22:00:27

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

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

FDA-CBER-2022-1614-0082327

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **18 Apr 2021 19:13:25**
Generated On: 11 Aug 2021 22:00:27

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

	Intramuscular ☐
	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 2000
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 ■

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **18 Apr 2021 19:13:25**
Generated On: 11 Aug 2021 22:00:27

Name of Medication	VITAMIN C
Prophylaxis	Yes ■ No ☐
Indication	GENERAL HEALTH
Dose per administration	1000
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-0082330

	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 2017
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 ■

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **18 Apr 2021 19:13:25**
Generated On: 11 Aug 2021 22:00:27

Name of Medication	VITAMIN D
Prophylaxis	Yes ■ No ☐
Indication	GENERAL HEALTH
Dose per administration	2000
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 ☐

FDA-CBER-2022-1614-0082332

	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 2017
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	OCUVITE - EXACT INGREDIENTS UNKNOWN
Prophylaxis	Yes ■ No ☐
Indication	GENERAL EYE HEALTH
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ■ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
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 2017
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 ■

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **18 Apr 2021 19:13:25**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082336

	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 2017
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 ■

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **18 Apr 2021 19:13:25**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082338

	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 ■

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **18 Apr 2021 19:13:25**
Generated On: 11 Aug 2021 22:00:27

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

FDA-CBER-2022-1614-0082340

	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 2017
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 ■

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **18 Apr 2021 19:13:25**
Generated On: 11 Aug 2021 22:00:27

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ■
Indication	SITE INJECTION PAIN
Dose per administration	1000
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-0082342

	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)*	5 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	5 AUG 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 ☐

US3142056
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **18 Apr 2021 19:13:25**
Generated On: 11 Aug 2021 22:00:27

Were any concomitant procedures performed?	Yes ☐ No ■

If yes, please complete Concomitant Procedures form.

US3142056
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 11 Aug 2021 22:00:27

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	

Date of study discontinuation/completion *(dd MMM yyyy)*	
Reason for discontinuation	AE (specify) ☐ SAE (specify) ☐ Complete ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	
If reason for discontinuation is Death, main cause of death	Adverse event ☐ Unknown ☐ Other ☐
If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	
Was autopsy performed?	Yes ☐ No ☐ Unknown ☐

FDA-CBER-2022-1614-0082346

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

SAEID	USA-US064-2021-MRNA-1273-P301000008
Serious	Yes ☐ No ■
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form (1)
Data signed: (b) (4) **18 Apr 2021 19:13:50**
Generated On: 11 Aug 2021 22:00:27

SAEID	USA-US064-2021-MRNA-1273-P301000008
Serious	Yes ☐ No ■
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	29/MAR/2021 12:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3142056 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

US3142056
Form: Participant Creation
Generated On: 11 Aug 2021 22:00:27
Participant ID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:21:57
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'US3142056'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 14:19:31

FDA-CBER-2022-1614-0082350

US3142056
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 14:41:34

FDA-CBER-2022-1614-0082351

US3142056
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '03 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 14:19:32

FDA-CBER-2022-1614-0082352

US3142056
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	03 Aug 2020 14:41:34

US3142056
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'SCRN'	System	03 Aug 2020 14:41:34

US3142056
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:00:27
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '(b) (6)1962'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 14:19:33

FDA-CBER-2022-1614-0082355

US3142056
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:00:27
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '58'	(b) (4), (b) (6)	03 Aug 2020 14:42:02

US3142056
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:00:27
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'YEARS'	System	03 Aug 2020 14:42:02

US3142056
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:00:27
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '58'	System	03 Aug 2020 14:42:41

US3142056
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:00:27
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Male (M)'	(b) (4), (b) (6)	03 Aug 2020 14:42:02

US3142056
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:00:27
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	03 Aug 2020 14:42:02

US3142056
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:00:27
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '1'	(b) (4), (b) (6)	03 Aug 2020 14:42:02

US3142056
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:00:27
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 14:42:02

US3142056
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:00:27
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 14:42:02

US3142056
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:00:27
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 14:42:02

US3142056
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:00:27
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 14:42:02

US3142056
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:00:27
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 14:42:02

US3142056
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:00:27
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 14:42:02

US3142056
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:00:27
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 14:42:02

US3142056
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:00:27
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 14:42:02

US3142056
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:00:27
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '03 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 14:42:41

US3142056
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:00:27
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'Aug 2020'	System	03 Aug 2020 14:42:41

US3142056
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:00:27
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '2020'	System	03 Aug 2020 14:42:41

US3142056
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:00:27
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	09 Dec 2020 22:58:02
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	03 Aug 2020 14:42:41

US3142056
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:00:27
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 14:42:41

US3142056
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:00:27
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 14:42:41

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US3142056
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:00:27
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 14:42:41

US3142056
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:00:27
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 14:42:41

FDA-CBER-2022-1614-0082377

US3142056
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:00:27
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 14:19:32

FDA-CBER-2022-1614-0082378

US3142056
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:00:27
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '1'	System	03 Aug 2020 14:42:55

US3142056
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 11 Aug 2021 22:00:27
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 14:42:55

US3142056
Folder: Screening
Form: Medical History Summary
Generated On: 11 Aug 2021 22:00:27
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 18:50:31

US3142056
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:00:27
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Per DM CLR: Please specify the laterality of eye that is NEARSIGHTED. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:16:20
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 17:57:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 17:57:13
Data point term sent to Coder	System	07 Oct 2020 17:56:01
Query 'Per DM CLR: Please specify the laterality of eye that is NEARSIGHTED. Review and update Med History eCRF as appropriate. ' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	07 Oct 2020 17:55:33
Coding entries removed.	Meghan York (b) (4) (b) (4)	07 Oct 2020 17:55:25
User entered 'NEARSIGHTED bilateral' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	07 Oct 2020 17:55:25
User opened query 'Per DM CLR: Please specify the laterality of eye that is NEARSIGHTED. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 08:33:31
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:53:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:53:09
Data point term sent to Coder	System	03 Aug 2020 18:52:11
User entered 'Nearsighted'	(b) (4), (b) (6)	03 Aug 2020 18:51:51

US3142056
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:00:27
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'un UNK 1972'	(b) (4), (b) (6)	03 Aug 2020 18:51:51

US3142056
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:00:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 18:51:51

US3142056
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:00:27
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 18:51:51

US3142056
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:00:27
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 18:51:51

US3142056
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:00:27
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 18:51:51

US3142056
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:00:27
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'Jan 1972'	System	03 Aug 2020 18:51:51

US3142056
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:00:27
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '1972'	System	03 Aug 2020 18:51:51

US3142056
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:00:27
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered empty.	System	03 Aug 2020 18:51:51

US3142056
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:00:27
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered empty.	System	03 Aug 2020 18:51:51

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US3142056
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:00:27
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 22:16:27
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'subject did not indicate any medication for this condition ' (Site from DM).	Meghan York (b) (4) (b) (4)	07 Oct 2020 17:57:32
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 08:34:22
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:54:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:54:12
Data point term sent to Coder	System	03 Aug 2020 18:53:11
User entered 'Asthma'	(b) (4), (b) (6)	03 Aug 2020 18:52:26

FDA-CBER-2022-1614-0082392

US3142056
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:00:27
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'un UNK 1974'	(b) (4), (b) (6)	03 Aug 2020 18:52:26

US3142056
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:00:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 18:52:26

US3142056
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:00:27
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 18:52:26

US3142056
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:00:27
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 18:52:26

US3142056
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:00:27
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 18:52:26

US3142056
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:00:27
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'Jan 1974'	System	03 Aug 2020 18:52:26

US3142056
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:00:27
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '1974'	System	03 Aug 2020 18:52:26

US3142056
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:00:27
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered empty.	System	03 Aug 2020 18:52:26

US3142056
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:00:27
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered empty.	System	03 Aug 2020 18:52:26

US3142056
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:00:27
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:54:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:54:12
Data point term sent to Coder	System	03 Aug 2020 18:53:11
User entered 'Seasonal Allergies'	(b) (4), (b) (6)	03 Aug 2020 18:52:56

US3142056
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:00:27
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'un UNK 2015'	(b) (4), (b) (6)	03 Aug 2020 18:52:56

US3142056
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:00:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 18:52:56

US3142056
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:00:27
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 18:52:56

US3142056
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:00:27
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 18:52:56

US3142056
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:00:27
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 18:52:56

US3142056
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:00:27
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'Jan 2015'	System	03 Aug 2020 18:52:56

US3142056
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:00:27
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '2015'	System	03 Aug 2020 18:52:56

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US3142056
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:00:27
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered empty.	System	03 Aug 2020 18:52:56

US3142056
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:00:27
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered empty.	System	03 Aug 2020 18:52:56

US3142056
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:00:27
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Tooth missing, PT: Tooth loss, LLT: Tooth loss - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:55:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:55:02
Data point term sent to Coder	System	03 Aug 2020 18:54:12
User entered 'Tooth loss'	(b) (4), (b) (6)	03 Aug 2020 18:53:37

US3142056
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:00:27
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'un UNK 2015'	(b) (4), (b) (6)	03 Aug 2020 18:53:37

US3142056
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:00:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 18:53:37

US3142056
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:00:27
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	03 Aug 2020 18:57:07
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	03 Aug 2020 18:53:37
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 18:53:37

US3142056
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:00:27
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'un UNK 2015' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 18:57:07
User entered empty.		03 Aug 2020 18:53:37

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US3142056
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:00:27
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 18:53:37

US3142056
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:00:27
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'Jan 2015'	System	03 Aug 2020 18:53:37

US3142056
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:00:27
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '2015'	System	03 Aug 2020 18:53:37

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US3142056
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:00:27
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'Jan 2015'	System	03 Aug 2020 18:57:07
User entered empty.	System	03 Aug 2020 18:53:37

FDA-CBER-2022-1614-0082420

US3142056
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:00:27
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '2015'	System	03 Aug 2020 18:57:07
User entered empty.	System	03 Aug 2020 18:53:37

US3142056
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:00:27
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User closed query 'Per CDM: Response noted. Please update the MHx condition with any corresponding AE or ConMed entries, if applicable. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 16:25:57
Query 'Per CDM: Response noted. Please update the MHx condition with any corresponding AE or ConMed entries, if applicable. Thank you.' answered with 'subject did not indicate any medication for this condition. Not considered an AE' (Site from DM).	Meghan York (b) (4) (b) (4)	13 Oct 2020 16:25:42
User opened query 'Per CDM: Response noted. Please update the MHx condition with any corresponding AE or ConMed entries, if applicable. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:18:24
User closed query 'Per DM CLR: Please clarify location/type of RIGHT HERNIA (e.g. inguinal, femoral, umbilical, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).		13 Oct 2020 03:16:36
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Right inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 18:00:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 18:00:21
Data point term sent to Coder	System	07 Oct 2020 17:59:05
Query 'Per DM CLR: Please clarify location/type of RIGHT HERNIA (e.g. inguinal, femoral, umbilical, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	07 Oct 2020 17:58:19
Coding entries removed.	Meghan York (b) (4) (b) (4)	07 Oct 2020 17:58:11
User entered 'RIGHT HERNIA inguinal' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	07 Oct 2020 17:58:11

US3142056
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:00:27
Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please clarify location/type of RIGHT HERNIA (e.g. inguinal, femoral, umbilical, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 08:34:48
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Hernias NEC, PT: Hernia, LLT: Hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 21:56:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 21:56:20
Data point term sent to Coder	System	03 Aug 2020 18:55:13
User entered 'Right Hernia'	(b) (4), (b) (6)	03 Aug 2020 18:54:23

US3142056
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:00:27
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'UN UNK 1984' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 18:57:50
User entered 'un UNK 2000'		03 Aug 2020 18:54:23

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US3142056
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:00:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 18:54:23

US3142056
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:00:27
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	03 Aug 2020 18:57:50
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	03 Aug 2020 18:54:23
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 18:54:23

US3142056
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:00:27
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'un UNK 1984' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 18:57:50
User entered empty.		03 Aug 2020 18:54:23

FDA-CBER-2022-1614-0082427

US3142056
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:00:27
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 18:54:23

US3142056
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:00:27
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'Jan 1984'	System	03 Aug 2020 18:57:50
User entered 'Jan 2000'	System	03 Aug 2020 18:54:23

US3142056
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:00:27
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '1984'	System	03 Aug 2020 18:57:50
User entered '2000'	System	03 Aug 2020 18:54:23

US3142056
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:00:27
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'Jan 1984'	System	03 Aug 2020 18:57:50
User entered empty.	System	03 Aug 2020 18:54:23

US3142056
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:00:27
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '1984'	System	03 Aug 2020 18:57:50
User entered empty.	System	03 Aug 2020 18:54:23

US3142056
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 22:00:27
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:56:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:56:05
Data point term sent to Coder	System	03 Aug 2020 18:55:13
User entered 'Headaches'	(b) (4), (b) (6)	03 Aug 2020 18:55:04

US3142056
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 22:00:27
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'un UNK 1985'	(b) (4), (b) (6)	03 Aug 2020 18:55:04

US3142056
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 22:00:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 18:55:04

US3142056
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 22:00:27
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 18:55:04

US3142056
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 22:00:27
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 18:55:04

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US3142056
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 22:00:27
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 18:55:04

US3142056
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 22:00:27
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'Jan 1985'	System	03 Aug 2020 18:55:04

US3142056
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 22:00:27
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '1985'	System	03 Aug 2020 18:55:04

US3142056
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 22:00:27
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered empty.	System	03 Aug 2020 18:55:04

US3142056
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 22:00:27
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered empty.	System	03 Aug 2020 18:55:04

US3142056
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 22:00:27
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:57:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:57:02
Data point term sent to Coder	System	03 Aug 2020 18:56:14
User entered 'Erectile Dysfunction'	(b) (4), (b) (6)	03 Aug 2020 18:55:47

US3142056
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 22:00:27
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'un UNK 2013'	(b) (4), (b) (6)	03 Aug 2020 18:55:47

US3142056
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 22:00:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 18:55:47

US3142056
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 22:00:27
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 18:55:47

US3142056
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 22:00:27
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 18:55:47

US3142056
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 22:00:27
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 18:55:47

US3142056
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 22:00:27
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'Jan 2013'	System	03 Aug 2020 18:55:47

US3142056
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 22:00:27
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '2013'	System	03 Aug 2020 18:55:47

US3142056
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 22:00:27
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered empty.	System	03 Aug 2020 18:55:47

US3142056
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 22:00:27
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered empty.	System	03 Aug 2020 18:55:47

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US3142056
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 22:00:27
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:58:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:58:03
Data point term sent to Coder	System	03 Aug 2020 18:57:15
User entered 'GERD'	(b) (4), (b) (6)	03 Aug 2020 18:56:29

US3142056
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 22:00:27
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'un UNK 2000'	(b) (4), (b) (6)	03 Aug 2020 18:56:29

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US3142056
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 22:00:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 18:56:29

US3142056
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 22:00:27
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 18:56:29

US3142056
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 22:00:27
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 18:56:29

FDA-CBER-2022-1614-0082457

US3142056
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 22:00:27
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 18:56:29

US3142056
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 22:00:27
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'Jan 2000'	System	03 Aug 2020 18:56:29

US3142056
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 22:00:27
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '2000'	System	03 Aug 2020 18:56:29

US3142056
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 22:00:27
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered empty.	System	03 Aug 2020 18:56:29

US3142056
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 22:00:27
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered empty.	System	03 Aug 2020 18:56:29

US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 18:50:10

US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '03 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 18:50:10

US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '08:55'	(b) (4), (b) (6)	03 Aug 2020 18:50:10

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US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '03 Aug 2020 08:55'	System	03 Aug 2020 18:50:10

US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '74' in	(b) (4), (b) (6)	03 Aug 2020 18:50:10
DataPoint set to visible.	System	03 Aug 2020 14:42:55

US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '249' lb	(b) (4), (b) (6)	03 Aug 2020 18:50:10
DataPoint set to visible.	System	03 Aug 2020 14:42:55

US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
Amendment Manager: User entered '32.03655'	System	16 Sep 2020 23:41:00
User entered '32.0'	System	03 Aug 2020 18:50:10
DataPoint set to visible.	System	03 Aug 2020 14:42:55

US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'kg/m2'	System	03 Aug 2020 18:50:10
DataPoint set to visible.	System	03 Aug 2020 14:42:55

US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 02:20:27
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:31:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:30:55
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 14:21:53
User entered '98.3' F		03 Aug 2020 18:50:10

US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:30:55
User entered 'Other (Other)'	(b) (4), (b) (6)	03 Aug 2020 18:50:10

FDA-CBER-2022-1614-0082472

US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:30:55
User entered 'Temporal'	(b) (4), (b) (6)	03 Aug 2020 18:50:10

US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:30:55
User entered '57'	(b) (4), (b) (6)	03 Aug 2020 18:50:10

US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'bpm'	System	03 Aug 2020 18:50:10

FDA-CBER-2022-1614-0082475

US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:30:55
User entered '18'	(b) (4), (b) (6)	03 Aug 2020 18:50:10

US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'breaths/min'	System	03 Aug 2020 18:50:10

FDA-CBER-2022-1614-0082477

US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:30:55
User entered '123'	(b) (4), (b) (6)	03 Aug 2020 18:50:10

FDA-CBER-2022-1614-0082478

US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'mmHg'	System	03 Aug 2020 18:50:10

FDA-CBER-2022-1614-0082479

US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:30:55
User entered '73'	(b) (4), (b) (6)	03 Aug 2020 18:50:10

US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'mmHg'	System	03 Aug 2020 18:50:10

US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38

FDA-CBER-2022-1614-0082482

US3142056
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38

FDA-CBER-2022-1614-0082483

US3142056
Folder: Screening
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 18:48:47

US3142056
Folder: Screening
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '03 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 18:48:47

FDA-CBER-2022-1614-0082485

US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 14:43:52

US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 14:43:52

US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
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)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 14:43:52

US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
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)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 14:43:52

US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 14:43:52

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US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
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)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 14:43:52

US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
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)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 14:43:52

US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
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)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 14:43:52

US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
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)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 14:43:52

US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
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)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 14:43:52

US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
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)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 14:43:52

US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 14:43:52

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US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 14:43:52

FDA-CBER-2022-1614-0082498

US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 14:43:52

US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 14:43:52

US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
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)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 14:43:52

US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
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)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 14:43:52

US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
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)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 14:43:52

US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '1'	(b) (4), (b) (6)	03 Aug 2020 14:43:52

US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 14:43:52

US3142056
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:00:27
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 14:43:52

US3142056
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 18:58:33

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US3142056
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '3 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 18:58:33

US3142056
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	03 Aug 2020 18:58:33

US3142056
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered 'VISIT1'	System	03 Aug 2020 18:58:33

FDA-CBER-2022-1614-0082510

US3142056
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:00:27
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '03 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 16:14:51

US3142056
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:00:27
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:43:11
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:43:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Aug 2020 16:14:51
User entered '142604' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 16:14:51

US3142056
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:00:27
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	07 Oct 2020 18:00:30
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered by data change (Site from System).	System	07 Oct 2020 18:00:30
Amendment Manager: User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	30 Sep 2020 21:10:10
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	30 Sep 2020 21:10:10
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	03 Aug 2020 18:59:06
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 16:14:51

US3142056
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:00:27
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)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'as per MEDHX form, subject suffers from asthma since 1974. please confirm if this condition meets the risk criteria noted on this form. please confirm if this answer should be yes based on MEDHx. CMED does not note a use of medications to control.' (Site from CRA).	(b) (4), (b) (6)	12 Oct 2020 22:31:36
Query 'as per MEDHX form, subject suffers from asthma since 1974. please confirm if this condition meets the risk criteria noted on this form. please confirm if this answer should be yes based on MEDHx. CMED does not note a use of medications to control.' answered with 'fixed ' (Site from CRA).	Meghan York (b) (4) (b) (4)	07 Oct 2020 18:00:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	07 Oct 2020 18:00:30
User opened query 'as per MEDHX form, subject suffers from asthma since 1974. please confirm if this condition meets the risk criteria noted on this form. please confirm if this answer should be yes based on MEDHx. CMED does not note a use of medications to control.' (Site from CRA).	(b) (4), (b) (6)	11 Aug 2020 00:06:41
Query 'as per MEDHX form, subject suffers from asthma since 1974. please confirm if this condition meets the risk criteria noted on this form. please confirm if this answer should be yes based on MEDHx' canceled (Site from CRA).		11 Aug 2020 00:05:41
User opened query 'as per MEDHX form, subject suffers from asthma since 1974. please confirm if this condition meets the risk criteria noted on this form. please confirm if this answer should be yes based on MEDHx' (Site from CRA).		10 Aug 2020 23:34:12
User entered 'No (N)'		03 Aug 2020 18:59:06

US3142056
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:00:27
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)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 18:59:06

US3142056
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:00:27
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 18:59:06

FDA-CBER-2022-1614-0082516

US3142056
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:00:27
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 18:59:06

FDA-CBER-2022-1614-0082517

US3142056
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:00:27
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 18:59:06

FDA-CBER-2022-1614-0082518

US3142056
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:00:27
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
DataPoint set to visible.	System	09 Dec 2020 22:58:02
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 03:21:51

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:00:27
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 16:33:04
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:31:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:31:15
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 06:47:32
User entered '74' in		03 Aug 2020 19:02:32

FDA-CBER-2022-1614-0082520

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:00:27
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:31:15
User entered '249' lb	(b) (4), (b) (6)	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:00:27
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 16:33:04
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:31:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:31:15
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 06:47:32
User entered '74' in		03 Aug 2020 19:02:32

FDA-CBER-2022-1614-0082522

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:00:27
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:31:15
User entered '249' lb	(b) (4), (b) (6)	03 Aug 2020 19:02:32

FDA-CBER-2022-1614-0082523

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User accepted default value 'Pre-Dose (PREDOSE)'		03 Aug 2020 19:02:32

FDA-CBER-2022-1614-0082524

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '03 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 19:02:32

FDA-CBER-2022-1614-0082526

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '08:55'	(b) (4), (b) (6)	03 Aug 2020 19:02:32

FDA-CBER-2022-1614-0082527

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered '03 Aug 2020 08:55'	System	03 Aug 2020 19:02:32

FDA-CBER-2022-1614-0082528

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered '98.3' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Aug 2020 19:07:57
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:04:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Aug 2020 19:04:02
User entered '97.7' F reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 19:04:02
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:02:32
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:04:02
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 19:04:02
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:02:32
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Temporal' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 19:04:02
User entered empty.		03 Aug 2020 19:02:32

FDA-CBER-2022-1614-0082531

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '57' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 19:07:57
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:04:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Aug 2020 19:04:02
User entered '56' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 19:04:02
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:02:32
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:02:32

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US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered 'bpm'	System	03 Aug 2020 19:04:02
User entered empty.	System	03 Aug 2020 19:02:32

FDA-CBER-2022-1614-0082533

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 19:07:57
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:04:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Aug 2020 19:04:02
User entered '24' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 19:04:02
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:02:32
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered 'breaths/min'	System	03 Aug 2020 19:04:02
User entered empty.	System	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '123' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 19:07:57
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:04:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Aug 2020 19:04:02
User entered '143' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 19:04:02
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:02:32
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered 'mmHg'	System	03 Aug 2020 19:04:02
User entered empty.	System	03 Aug 2020 19:02:32

FDA-CBER-2022-1614-0082537

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '73' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 19:07:57
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:04:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Aug 2020 19:04:02
User entered '96' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 19:04:02
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:02:32
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered 'mmHg'	System	03 Aug 2020 19:04:02
User entered empty.	System	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:00:27
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 16:33:04
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:31:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:31:15
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 06:47:32
User entered '74' in		03 Aug 2020 19:02:32

FDA-CBER-2022-1614-0082540

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:00:27
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:31:15
User entered '249' lb	(b) (4), (b) (6)	03 Aug 2020 19:02:32

FDA-CBER-2022-1614-0082541

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User accepted default value 'Post-Dose (POSTDOSE)'		03 Aug 2020 19:02:32

FDA-CBER-2022-1614-0082542

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '03 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	17 Aug 2020 23:54:01
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	03 Aug 2020 19:02:32
User entered '10:51'	(b) (4), (b) (6)	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered '03 Aug 2020 10:51'	System	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:06:40
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Aug 2020 19:06:40
User entered '97.7' F reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 19:06:40
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:02:32
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:06:40
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 19:06:40
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:02:32
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Temporal' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 19:06:40
User entered empty.		03 Aug 2020 19:02:32

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US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:06:40
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Aug 2020 19:06:40
User entered '56' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 19:06:40
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:02:32
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered 'bpm'	System	03 Aug 2020 19:06:40
User entered empty.	System	03 Aug 2020 19:02:32

FDA-CBER-2022-1614-0082551

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:06:40
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Aug 2020 19:06:40
User entered '24' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 19:06:40
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:02:32
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered 'breaths/min'	System	03 Aug 2020 19:06:40
User entered empty.	System	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:06:40
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Aug 2020 19:06:40
User entered '143' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 19:06:40
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:02:32
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered 'mmHg'	System	03 Aug 2020 19:06:40
User entered empty.	System	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:06:40
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Aug 2020 19:06:40
User entered '96' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 19:06:40
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 19:02:32
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered 'mmHg'	System	03 Aug 2020 19:06:40
User entered empty.	System	03 Aug 2020 19:02:32

US3142056
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:31:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 19:08:48

US3142056
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:31:31
User entered '03 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 19:08:48

US3142056
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	03 Aug 2020 16:30:51

US3142056
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Meghan York (b) (4) (b) (4)	03 Aug 2020 16:30:51

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US3142056
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
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)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Meghan York (b) (4) (b) (4)	03 Aug 2020 16:30:51

US3142056
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered 'MRNA-1273 OR PLACEBO'	System	03 Aug 2020 16:30:51

US3142056
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '3 Aug 2020'	Meghan York (b) (4) (b) (4)	03 Aug 2020 16:30:51

US3142056
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '10:19'	Meghan York (b) (4) (b) (4)	03 Aug 2020 16:30:51

US3142056
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered '3 Aug 2020 10:19'	System	03 Aug 2020 16:30:51

US3142056
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Left Arm (LEFT ARM)'	Meghan York (b) (4) (b) (4)	03 Aug 2020 16:30:51

US3142056
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered 'ONCE'	System	03 Aug 2020 16:30:51

US3142056
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered 'INTRAMUSCULAR'	System	03 Aug 2020 16:30:51

US3142056
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:00:27
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 19:09:15

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US3142056
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:00:27
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '03 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 19:09:15

FDA-CBER-2022-1614-0082571

US3142056
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:00:27
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '10:03'	(b) (4), (b) (6)	03 Aug 2020 19:09:15

FDA-CBER-2022-1614-0082572

US3142056
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:00:27
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered '03 Aug 2020 10:03'	System	03 Aug 2020 19:09:15

US3142056
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 11 Aug 2021 22:00:27
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '03 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 19:09:47

US3142056
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:00:27
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		03 Aug 2020 19:09:47

FDA-CBER-2022-1614-0082575

US3142056
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:00:27
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 19:09:47

US3142056
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:00:27
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '10:03'	(b) (4), (b) (6)	03 Aug 2020 19:09:47

FDA-CBER-2022-1614-0082577

US3142056
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:00:27
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered '03 Aug 2020 10:03'	System	03 Aug 2020 19:09:47

US3142056
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:00:27
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		03 Aug 2020 19:09:47

FDA-CBER-2022-1614-0082579

US3142056
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:00:27
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 19:09:47

FDA-CBER-2022-1614-0082580

US3142056
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:00:27
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '10:03'	(b) (4), (b) (6)	03 Aug 2020 19:09:47

FDA-CBER-2022-1614-0082581

US3142056
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:00:27
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered '03 Aug 2020 10:03'	System	03 Aug 2020 19:09:47

US3142056
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 19:09:58

FDA-CBER-2022-1614-0082583

US3142056
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered '1'	System	03 Aug 2020 19:09:58

FDA-CBER-2022-1614-0082584

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082585

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T10:52:37', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '29e61e01-9a0c-40c7-8564-5ddfc25f95f3'	System	03 Aug 2020 16:53:16
User entered 'Yes (Y)'	System	03 Aug 2020 16:53:16

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T10:52:52', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '29e61e01-9a0c-40c7-8564-5ddfc25f95f3'	System	03 Aug 2020 16:53:16
User entered '97.6'	System	03 Aug 2020 16:53:16

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T10:53:01', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '29e61e01-9a0c-40c7-8564-5ddfc25f95f3'	System	03 Aug 2020 16:53:16
User entered 'No (N)'	System	03 Aug 2020 16:53:16

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T10:53:12', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '29e61e01-9a0c-40c7-8564-5ddfc25f95f3'	System	03 Aug 2020 16:53:16
User entered '03 Aug 2020 10:53'	System	03 Aug 2020 16:53:16

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '03 Aug 2020 10:39'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '03 Aug 2020 13:09'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T20:17:12', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'c418ab00-2948-4de6-9a43-7ee4885c79bb'	System	04 Aug 2020 02:17:34
User entered 'Yes (Y)'	System	04 Aug 2020 02:17:34

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T20:17:18', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'c418ab00-2948-4de6-9a43-7ee4885c79bb'	System	04 Aug 2020 02:17:34
User entered '96.6'	System	04 Aug 2020 02:17:34

FDA-CBER-2022-1614-0082594

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T20:17:21', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'c418ab00-2948-4de6-9a43-7ee4885c79bb'	System	04 Aug 2020 02:17:34
User entered 'No (N)'	System	04 Aug 2020 02:17:34

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T20:17:29', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'c418ab00-2948-4de6-9a43-7ee4885c79bb'	System	04 Aug 2020 02:17:34
User entered '03 Aug 2020 20:17'	System	04 Aug 2020 02:17:34

FDA-CBER-2022-1614-0082596

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '03 Aug 2020 14:04'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082597

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082598

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 2'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082599

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:00:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-04T21:52:42', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'bf7642da-e56b-4e8b-b56b-ad38c7e51002'	System	05 Aug 2020 03:53:01
User entered 'Yes (Y)'	System	05 Aug 2020 03:53:01

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:00:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-04T21:52:48', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'bf7642da-e56b-4e8b-b56b-ad38c7e51002'	System	05 Aug 2020 03:53:01
User entered '96.7'	System	05 Aug 2020 03:53:01

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:00:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-04T21:52:51', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'bf7642da-e56b-4e8b-b56b-ad38c7e51002'	System	05 Aug 2020 03:53:01
User entered 'No (N)'	System	05 Aug 2020 03:53:01

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US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-04T21:52:56', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'bf7642da-e56b-4e8b-b56b-ad38c7e51002'	System	05 Aug 2020 03:53:01
User entered '04 Aug 2020 21:52'	System	05 Aug 2020 03:53:01

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082604

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 3'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:00:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-05T21:53:24', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '883e229b-baa6-46a5-a69b-005c41e24224'	System	06 Aug 2020 03:54:04
User entered 'Yes (Y)'	System	06 Aug 2020 03:54:04

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:00:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-05T21:53:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '883e229b-baa6-46a5-a69b-005c41e24224'	System	06 Aug 2020 03:54:04
User entered '95.9'	System	06 Aug 2020 03:54:04

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:00:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-05T21:53:38', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '883e229b-baa6-46a5-a69b-005c41e24224'	System	06 Aug 2020 03:54:04
User entered 'Yes (Y)'	System	06 Aug 2020 03:54:04

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:00:27
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
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).		23 Nov 2020 14:39:27
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'conmed added' (Site from System).	Jill York (b) (4)	16 Nov 2020 22:44:30
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	06 Aug 2020 03:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-05T21:53:43', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '883e229b-baa6-46a5-a69b-005c41e24224'	System	06 Aug 2020 03:54:04
User entered '1'	System	06 Aug 2020 03:54:04

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US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:00:27
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-05T21:53:43', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '883e229b-baa6-46a5-a69b-005c41e24224'	System	06 Aug 2020 03:54:04
User entered '0'	System	06 Aug 2020 03:54:04

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-05T21:53:58', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '883e229b-baa6-46a5-a69b-005c41e24224'	System	06 Aug 2020 03:54:04
User entered '05 Aug 2020 21:53'	System	06 Aug 2020 03:54:04

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082614

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 4'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:00:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-06T21:30:46', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6b9cf670-af16-45f7-92d6-de99dfa63e50'	System	07 Aug 2020 03:31:02
User entered 'Yes (Y)'	System	07 Aug 2020 03:31:02

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:00:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-06T21:30:51', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6b9cf670-af16-45f7-92d6-de99dfa63e50'	System	07 Aug 2020 03:31:02
User entered '95.4'	System	07 Aug 2020 03:31:02

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:00:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-06T21:30:54', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6b9cf670-af16-45f7-92d6-de99dfa63e50'	System	07 Aug 2020 03:31:02
User entered 'No (N)'	System	07 Aug 2020 03:31:02

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-06T21:30:58', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6b9cf670-af16-45f7-92d6-de99dfa63e50'	System	07 Aug 2020 03:31:02
User entered '06 Aug 2020 21:30'	System	07 Aug 2020 03:31:02

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 5'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:00:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-08T01:29:01', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '8914e266-aa95-45da-adc8-0b829f36671a'	System	08 Aug 2020 07:29:33
User entered 'Yes (Y)'	System	08 Aug 2020 07:29:33

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:00:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-08T01:29:14', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '8914e266-aa95-45da-adc8-0b829f36671a'	System	08 Aug 2020 07:29:33
User entered '96.9'	System	08 Aug 2020 07:29:33

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:00:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-08T01:29:22', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '8914e266-aa95-45da-adc8-0b829f36671a'	System	08 Aug 2020 07:29:33
User entered 'No (N)'	System	08 Aug 2020 07:29:33

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-08T01:29:26', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '8914e266-aa95-45da-adc8-0b829f36671a'	System	08 Aug 2020 07:29:33
User entered '08 Aug 2020 01:29'	System	08 Aug 2020 07:29:33

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 6'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:00:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-09T00:48:57', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '4eb686d1-dc6f-4d32-8bac-b802dfe222cb'	System	09 Aug 2020 06:49:12
User entered 'Yes (Y)'	System	09 Aug 2020 06:49:12

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:00:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-09T00:49:02', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '4eb686d1-dc6f-4d32-8bac-b802dfe222cb'	System	09 Aug 2020 06:49:12
User entered '97.0'	System	09 Aug 2020 06:49:12

FDA-CBER-2022-1614-0082631

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:00:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-09T00:49:04', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '4eb686d1-dc6f-4d32-8bac-b802dfe222cb'	System	09 Aug 2020 06:49:12
User entered 'No (N)'	System	09 Aug 2020 06:49:12

FDA-CBER-2022-1614-0082632

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-09T00:49:07', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '4eb686d1-dc6f-4d32-8bac-b802dfe222cb'	System	09 Aug 2020 06:49:12
User entered '09 Aug 2020 00:49'	System	09 Aug 2020 06:49:12

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082634

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082635

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 7'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082636

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:00:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-10T00:20:28', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '64256e29-ea74-42e8-ad38-ac499f9cba08'	System	10 Aug 2020 06:20:42
User entered 'Yes (Y)'	System	10 Aug 2020 06:20:42

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:00:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-10T00:20:31', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '64256e29-ea74-42e8-ad38-ac499f9cba08'	System	10 Aug 2020 06:20:42
User entered '96.0'	System	10 Aug 2020 06:20:42

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:00:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-10T00:20:34', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '64256e29-ea74-42e8-ad38-ac499f9cba08'	System	10 Aug 2020 06:20:42
User entered 'No (N)'	System	10 Aug 2020 06:20:42

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-10T00:20:38', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '64256e29-ea74-42e8-ad38-ac499f9cba08'	System	10 Aug 2020 06:20:42
User entered '10 Aug 2020 00:20'	System	10 Aug 2020 06:20:42

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US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082641

US3142056
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082642

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T10:53:27', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'd5a6d1fe-95b8-43b2-a5d4-3bf7477be562'	System	03 Aug 2020 16:54:18
User entered 'None (1)'	System	03 Aug 2020 16:54:18

FDA-CBER-2022-1614-0082644

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T10:54:05', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'd5a6d1fe-95b8-43b2-a5d4-3bf7477be562'	System	03 Aug 2020 16:54:18
User entered 'No (N)'	System	03 Aug 2020 16:54:18

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T10:54:08', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'd5a6d1fe-95b8-43b2-a5d4-3bf7477be562'	System	03 Aug 2020 16:54:18
User entered 'No (N)'	System	03 Aug 2020 16:54:18

FDA-CBER-2022-1614-0082646

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T10:54:11', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'd5a6d1fe-95b8-43b2-a5d4-3bf7477be562'	System	03 Aug 2020 16:54:18
User entered 'None (1)'	System	03 Aug 2020 16:54:18

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T10:54:16', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'd5a6d1fe-95b8-43b2-a5d4-3bf7477be562'	System	03 Aug 2020 16:54:18
User entered '03 Aug 2020 10:54'	System	03 Aug 2020 16:54:18

FDA-CBER-2022-1614-0082648

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '03 Aug 2020 10:39'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '03 Aug 2020 13:09'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082650

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T20:17:45', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '08416e04-b440-40cd-b7d7-0f1efa78f659'	System	04 Aug 2020 02:18:15
User entered 'Does not interfere with activity (2)'	System	04 Aug 2020 02:18:15

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US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T20:17:49', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '08416e04-b440-40cd-b7d7-0f1efa78f659'	System	04 Aug 2020 02:18:15
User entered 'No (N)'	System	04 Aug 2020 02:18:15

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T20:17:52', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '08416e04-b440-40cd-b7d7-0f1efa78f659'	System	04 Aug 2020 02:18:15
User entered 'No (N)'	System	04 Aug 2020 02:18:15

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T20:17:58', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '08416e04-b440-40cd-b7d7-0f1efa78f659'	System	04 Aug 2020 02:18:15
User entered 'None (1)'	System	04 Aug 2020 02:18:15

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T20:18:10', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '08416e04-b440-40cd-b7d7-0f1efa78f659'	System	04 Aug 2020 02:18:15
User entered '03 Aug 2020 20:18'	System	04 Aug 2020 02:18:15

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '03 Aug 2020 14:04'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082657

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 2'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082659

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-04T21:53:03', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '54531279-869a-4a50-95e4-b139be03d959'	System	05 Aug 2020 03:53:22
User entered 'None (1)'	System	05 Aug 2020 03:53:22

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:00:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-04T21:53:07', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '54531279-869a-4a50-95e4-b139be03d959'	System	05 Aug 2020 03:53:22
User entered 'No (N)'	System	05 Aug 2020 03:53:22

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:00:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-04T21:53:10', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '54531279-869a-4a50-95e4-b139be03d959'	System	05 Aug 2020 03:53:22
User entered 'No (N)'	System	05 Aug 2020 03:53:22

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-04T21:53:14', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '54531279-869a-4a50-95e4-b139be03d959'	System	05 Aug 2020 03:53:22
User entered 'None (1)'	System	05 Aug 2020 03:53:22

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-04T21:53:18', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '54531279-869a-4a50-95e4-b139be03d959'	System	05 Aug 2020 03:53:22
User entered '04 Aug 2020 21:53'	System	05 Aug 2020 03:53:22

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 3'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082667

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-05T21:54:07', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'fa5e2c94-11fe-431d-be51-50889f2e106d'	System	06 Aug 2020 03:54:41
User entered 'None (1)'	System	06 Aug 2020 03:54:41

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:00:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-05T21:54:12', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'fa5e2c94-11fe-431d-be51-50889f2e106d'	System	06 Aug 2020 03:54:41
User entered 'No (N)'	System	06 Aug 2020 03:54:41

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:00:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-05T21:54:15', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'fa5e2c94-11fe-431d-be51-50889f2e106d'	System	06 Aug 2020 03:54:41
User entered 'No (N)'	System	06 Aug 2020 03:54:41

FDA-CBER-2022-1614-0082670

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-05T21:54:21', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'fa5e2c94-11fe-431d-be51-50889f2e106d'	System	06 Aug 2020 03:54:41
User entered 'None (1)'	System	06 Aug 2020 03:54:41

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-05T21:54:37', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'fa5e2c94-11fe-431d-be51-50889f2e106d'	System	06 Aug 2020 03:54:41
User entered '05 Aug 2020 21:54'	System	06 Aug 2020 03:54:41

FDA-CBER-2022-1614-0082672

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082673

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082674

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 4'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-06T21:31:02', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'e1026359-732d-47e3-b817-55af81b749e9'	System	07 Aug 2020 03:31:18
User entered 'None (1)'	System	07 Aug 2020 03:31:18

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:00:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-06T21:31:05', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'e1026359-732d-47e3-b817-55af81b749e9'	System	07 Aug 2020 03:31:18
User entered 'No (N)'	System	07 Aug 2020 03:31:18

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:00:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-06T21:31:08', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'e1026359-732d-47e3-b817-55af81b749e9'	System	07 Aug 2020 03:31:18
User entered 'No (N)'	System	07 Aug 2020 03:31:18

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-06T21:31:13', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'e1026359-732d-47e3-b817-55af81b749e9'	System	07 Aug 2020 03:31:18
User entered 'None (1)'	System	07 Aug 2020 03:31:18

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-06T21:31:16', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'e1026359-732d-47e3-b817-55af81b749e9'	System	07 Aug 2020 03:31:18
User entered '06 Aug 2020 21:31'	System	07 Aug 2020 03:31:18

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 5'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-08T01:29:32', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '9098ec82-f528-4ec0-bad8-4e08eef40ff0'	System	08 Aug 2020 07:29:53
User entered 'None (1)'	System	08 Aug 2020 07:29:53

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:00:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-08T01:29:34', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '9098ec82-f528-4ec0-bad8-4e08eef40ff0'	System	08 Aug 2020 07:29:53
User entered 'No (N)'	System	08 Aug 2020 07:29:53

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:00:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-08T01:29:39', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '9098ec82-f528-4ec0-bad8-4e08eef40ff0'	System	08 Aug 2020 07:29:53
User entered 'No (N)'	System	08 Aug 2020 07:29:53

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-08T01:29:42', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '9098ec82-f528-4ec0-bad8-4e08eef40ff0'	System	08 Aug 2020 07:29:53
User entered 'None (1)'	System	08 Aug 2020 07:29:53

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-08T01:29:50', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '9098ec82-f528-4ec0-bad8-4e08eef40ff0'	System	08 Aug 2020 07:29:53
User entered '08 Aug 2020 01:29'	System	08 Aug 2020 07:29:53

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 6'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-09T00:49:12', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'f6b65e85-419a-4497-91ab-26a7ffe9fe39'	System	09 Aug 2020 06:49:27
User entered 'None (1)'	System	09 Aug 2020 06:49:27

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US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:00:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-09T00:49:14', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'f6b65e85-419a-4497-91ab-26a7ffe9fe39'	System	09 Aug 2020 06:49:27
User entered 'No (N)'	System	09 Aug 2020 06:49:27

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:00:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-09T00:49:16', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'f6b65e85-419a-4497-91ab-26a7ffe9fe39'	System	09 Aug 2020 06:49:27
User entered 'No (N)'	System	09 Aug 2020 06:49:27

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US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-09T00:49:18', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'f6b65e85-419a-4497-91ab-26a7ffe9fe39'	System	09 Aug 2020 06:49:27
User entered 'None (1)'	System	09 Aug 2020 06:49:27

FDA-CBER-2022-1614-0082695

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-09T00:49:22', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'f6b65e85-419a-4497-91ab-26a7ffe9fe39'	System	09 Aug 2020 06:49:27
User entered '09 Aug 2020 00:49'	System	09 Aug 2020 06:49:27

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082697

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 7'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-10T00:20:42', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '36541639-2f08-4faa-940f-c054d5ef80d5'	System	10 Aug 2020 06:21:42
User entered 'None (1)'	System	10 Aug 2020 06:21:42

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:00:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-10T00:20:44', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '36541639-2f08-4faa-940f-c054d5ef80d5'	System	10 Aug 2020 06:21:42
User entered 'No (N)'	System	10 Aug 2020 06:21:42

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:00:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-10T00:20:46', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '36541639-2f08-4faa-940f-c054d5ef80d5'	System	10 Aug 2020 06:21:42
User entered 'No (N)'	System	10 Aug 2020 06:21:42

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-10T00:20:48', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '36541639-2f08-4faa-940f-c054d5ef80d5'	System	10 Aug 2020 06:21:42
User entered 'None (1)'	System	10 Aug 2020 06:21:42

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-10T00:20:50', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '36541639-2f08-4faa-940f-c054d5ef80d5'	System	10 Aug 2020 06:21:42
User entered '10 Aug 2020 00:20'	System	10 Aug 2020 06:21:42

US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T10:54:21', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '47fcab76-841a-4bf2-a948-5827b49f84fa'	System	03 Aug 2020 16:54:47
User entered 'None (0)'	System	03 Aug 2020 16:54:47

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T10:54:24', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '47fcab76-841a-4bf2-a948-5827b49f84fa'	System	03 Aug 2020 16:54:47
User entered 'None (0)'	System	03 Aug 2020 16:54:47

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T10:54:27', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '47fcab76-841a-4bf2-a948-5827b49f84fa'	System	03 Aug 2020 16:54:47
User entered 'None (0)'	System	03 Aug 2020 16:54:47

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T10:54:29', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '47fcab76-841a-4bf2-a948-5827b49f84fa'	System	03 Aug 2020 16:54:47
User entered 'None (0)'	System	03 Aug 2020 16:54:47

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T10:54:32', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '47fcab76-841a-4bf2-a948-5827b49f84fa'	System	03 Aug 2020 16:54:47
User entered 'None (0)'	System	03 Aug 2020 16:54:47

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T10:54:34', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '47fcab76-841a-4bf2-a948-5827b49f84fa'	System	03 Aug 2020 16:54:47
User entered 'None (0)'	System	03 Aug 2020 16:54:47

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T10:54:38', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '47fcab76-841a-4bf2-a948-5827b49f84fa'	System	03 Aug 2020 16:54:47
User entered 'No (N)'	System	03 Aug 2020 16:54:47

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T10:54:42', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '47fcab76-841a-4bf2-a948-5827b49f84fa'	System	03 Aug 2020 16:54:47
User entered '03 Aug 2020 10:54'	System	03 Aug 2020 16:54:47

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '03 Aug 2020 10:39'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082716

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '03 Aug 2020 13:09'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082717

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User closed query 'subject reported HA and fatigue - please confirm if this HA was present at baseline and is considered and AE?' (Site from CRA).		02 Nov 2020 17:30:50
Query 'subject reported HA and fatigue - please confirm if this HA was present at baseline and is considered and AE?' answered with 'it is a solicited AE reported post dose' (Site from CRA).	Meghan York (b) (4) (b) (4)	29 Oct 2020 21:09:11
User opened query 'subject reported HA and fatigue - please confirm if this HA was present at baseline and is considered and AE?' (Site from CRA).	(b) (4), (b) (6)	20 Aug 2020 20:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T20:18:22', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'cf8e38a5-06c8-43a5-a580-c28b4a48d2ab'	System	04 Aug 2020 02:19:03
User entered 'No interference with activity (1)'	System	04 Aug 2020 02:19:03

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User closed query ' subject reported fatigue - please confirm if fatigue was present at baseline and is considered and AE?' (Site from CRA).		02 Nov 2020 17:30:56
Query ' subject reported fatigue - please confirm if fatigue was present at baseline and is considered and AE?' answered with 'it is a solicited AE' (Site from CRA).	Meghan York (b) (4) (b) (4)	29 Oct 2020 21:09:21
User opened query ' subject reported fatigue - please confirm if fatigue was present at baseline and is considered and AE?' (Site from CRA).	(b) (4), (b) (6)	20 Aug 2020 20:53:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T20:18:31', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'cf8e38a5-06c8-43a5-a580-c28b4a48d2ab'	System	04 Aug 2020 02:19:03
User entered 'No interference with activity (1)'	System	04 Aug 2020 02:19:03

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T20:18:35', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'cf8e38a5-06c8-43a5-a580-c28b4a48d2ab'	System	04 Aug 2020 02:19:03
User entered 'None (0)'	System	04 Aug 2020 02:19:03

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T20:18:39', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'cf8e38a5-06c8-43a5-a580-c28b4a48d2ab'	System	04 Aug 2020 02:19:03
User entered 'None (0)'	System	04 Aug 2020 02:19:03

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T20:18:41', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'cf8e38a5-06c8-43a5-a580-c28b4a48d2ab'	System	04 Aug 2020 02:19:03
User entered 'None (0)'	System	04 Aug 2020 02:19:03

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T20:18:44', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'cf8e38a5-06c8-43a5-a580-c28b4a48d2ab'	System	04 Aug 2020 02:19:03
User entered 'None (0)'	System	04 Aug 2020 02:19:03

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T20:18:51', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'cf8e38a5-06c8-43a5-a580-c28b4a48d2ab'	System	04 Aug 2020 02:19:03
User entered 'No (N)'	System	04 Aug 2020 02:19:03

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-03T20:18:57', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'cf8e38a5-06c8-43a5-a580-c28b4a48d2ab'	System	04 Aug 2020 02:19:03
User entered '03 Aug 2020 20:18'	System	04 Aug 2020 02:19:03

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '03 Aug 2020 14:04'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 2'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-04T21:53:27', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '891b55ab-0e80-47f3-81c4-8efc9802695c'	System	05 Aug 2020 03:53:59
User entered 'None (0)'	System	05 Aug 2020 03:53:59

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-04T21:53:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '891b55ab-0e80-47f3-81c4-8efc9802695c'	System	05 Aug 2020 03:53:59
User entered 'None (0)'	System	05 Aug 2020 03:53:59

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-04T21:53:34', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '891b55ab-0e80-47f3-81c4-8efc9802695c'	System	05 Aug 2020 03:53:59
User entered 'None (0)'	System	05 Aug 2020 03:53:59

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-04T21:53:38', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '891b55ab-0e80-47f3-81c4-8efc9802695c'	System	05 Aug 2020 03:53:59
User entered 'None (0)'	System	05 Aug 2020 03:53:59

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-04T21:53:40', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '891b55ab-0e80-47f3-81c4-8efc9802695c'	System	05 Aug 2020 03:53:59
User entered 'None (0)'	System	05 Aug 2020 03:53:59

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-04T21:53:43', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '891b55ab-0e80-47f3-81c4-8efc9802695c'	System	05 Aug 2020 03:53:59
User entered 'None (0)'	System	05 Aug 2020 03:53:59

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-04T21:53:49', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '891b55ab-0e80-47f3-81c4-8efc9802695c'	System	05 Aug 2020 03:53:59
User entered 'No (N)'	System	05 Aug 2020 03:53:59

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-04T21:53:55', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '891b55ab-0e80-47f3-81c4-8efc9802695c'	System	05 Aug 2020 03:53:59
User entered '04 Aug 2020 21:53'	System	05 Aug 2020 03:53:59

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082738

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082739

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 3'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-05T21:55:05', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '8a3098fe-1a63-4a32-8727-b9ef56d473f4'	System	06 Aug 2020 03:55:37
User entered 'Any use of prescription pain reliever or prevents daily activity (3)'	System	06 Aug 2020 03:55:37

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-05T21:55:09', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '8a3098fe-1a63-4a32-8727-b9ef56d473f4'	System	06 Aug 2020 03:55:37
User entered 'None (0)'	System	06 Aug 2020 03:55:37

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-05T21:55:14', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '8a3098fe-1a63-4a32-8727-b9ef56d473f4'	System	06 Aug 2020 03:55:37
User entered 'None (0)'	System	06 Aug 2020 03:55:37

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-05T21:55:16', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '8a3098fe-1a63-4a32-8727-b9ef56d473f4'	System	06 Aug 2020 03:55:37
User entered 'None (0)'	System	06 Aug 2020 03:55:37

FDA-CBER-2022-1614-0082744

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-05T21:55:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '8a3098fe-1a63-4a32-8727-b9ef56d473f4'	System	06 Aug 2020 03:55:37
User entered 'None (0)'	System	06 Aug 2020 03:55:37

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-05T21:55:23', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '8a3098fe-1a63-4a32-8727-b9ef56d473f4'	System	06 Aug 2020 03:55:37
User entered 'None (0)'	System	06 Aug 2020 03:55:37

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-05T21:55:28', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '8a3098fe-1a63-4a32-8727-b9ef56d473f4'	System	06 Aug 2020 03:55:37
User entered 'No (N)'	System	06 Aug 2020 03:55:37

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-05T21:55:33', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '8a3098fe-1a63-4a32-8727-b9ef56d473f4'	System	06 Aug 2020 03:55:37
User entered '05 Aug 2020 21:55'	System	06 Aug 2020 03:55:37

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 4'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-06T21:31:21', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ae570552-c14a-48a3-9e3e-9335c14af8d8'	System	07 Aug 2020 03:31:43
User entered 'None (0)'	System	07 Aug 2020 03:31:43

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-06T21:31:24', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ae570552-c14a-48a3-9e3e-9335c14af8d8'	System	07 Aug 2020 03:31:43
User entered 'None (0)'	System	07 Aug 2020 03:31:43

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-06T21:31:26', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ae570552-c14a-48a3-9e3e-9335c14af8d8'	System	07 Aug 2020 03:31:43
User entered 'None (0)'	System	07 Aug 2020 03:31:43

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-06T21:31:28', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ae570552-c14a-48a3-9e3e-9335c14af8d8'	System	07 Aug 2020 03:31:43
User entered 'None (0)'	System	07 Aug 2020 03:31:43

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-06T21:31:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ae570552-c14a-48a3-9e3e-9335c14af8d8'	System	07 Aug 2020 03:31:43
User entered 'None (0)'	System	07 Aug 2020 03:31:43

FDA-CBER-2022-1614-0082756

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-06T21:31:33', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ae570552-c14a-48a3-9e3e-9335c14af8d8'	System	07 Aug 2020 03:31:43
User entered 'None (0)'	System	07 Aug 2020 03:31:43

FDA-CBER-2022-1614-0082757

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-06T21:31:37', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ae570552-c14a-48a3-9e3e-9335c14af8d8'	System	07 Aug 2020 03:31:43
User entered 'No (N)'	System	07 Aug 2020 03:31:43

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-06T21:31:39', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ae570552-c14a-48a3-9e3e-9335c14af8d8'	System	07 Aug 2020 03:31:43
User entered '06 Aug 2020 21:31'	System	07 Aug 2020 03:31:43

FDA-CBER-2022-1614-0082759

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 5'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-08T01:30:09', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '38c63cad-4713-465c-8b8b-11f4b59f20f1'	System	08 Aug 2020 07:30:28
User entered 'None (0)'	System	08 Aug 2020 07:30:28

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-08T01:30:11', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '38c63cad-4713-465c-8b8b-11f4b59f20f1'	System	08 Aug 2020 07:30:28
User entered 'None (0)'	System	08 Aug 2020 07:30:28

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-08T01:30:13', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '38c63cad-4713-465c-8b8b-11f4b59f20f1'	System	08 Aug 2020 07:30:28
User entered 'None (0)'	System	08 Aug 2020 07:30:28

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-08T01:30:15', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '38c63cad-4713-465c-8b8b-11f4b59f20f1'	System	08 Aug 2020 07:30:28
User entered 'None (0)'	System	08 Aug 2020 07:30:28

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-08T01:30:18', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '38c63cad-4713-465c-8b8b-11f4b59f20f1'	System	08 Aug 2020 07:30:28
User entered 'None (0)'	System	08 Aug 2020 07:30:28

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-08T01:30:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '38c63cad-4713-465c-8b8b-11f4b59f20f1'	System	08 Aug 2020 07:30:28
User entered 'None (0)'	System	08 Aug 2020 07:30:28

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-08T01:30:22', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '38c63cad-4713-465c-8b8b-11f4b59f20f1'	System	08 Aug 2020 07:30:28
User entered 'No (N)'	System	08 Aug 2020 07:30:28

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-08T01:30:25', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '38c63cad-4713-465c-8b8b-11f4b59f20f1'	System	08 Aug 2020 07:30:28
User entered '08 Aug 2020 01:30'	System	08 Aug 2020 07:30:28

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082771

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

FDA-CBER-2022-1614-0082772

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 6'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-09T00:49:26', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '5d26f980-0b55-48fc-967c-7597d305385d'	System	09 Aug 2020 06:49:43
User entered 'None (0)'	System	09 Aug 2020 06:49:43

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-09T00:49:28', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '5d26f980-0b55-48fc-967c-7597d305385d'	System	09 Aug 2020 06:49:43
User entered 'None (0)'	System	09 Aug 2020 06:49:43

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-09T00:49:29', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '5d26f980-0b55-48fc-967c-7597d305385d'	System	09 Aug 2020 06:49:43
User entered 'None (0)'	System	09 Aug 2020 06:49:43

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-09T00:49:31', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '5d26f980-0b55-48fc-967c-7597d305385d'	System	09 Aug 2020 06:49:43
User entered 'None (0)'	System	09 Aug 2020 06:49:43

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-09T00:49:32', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '5d26f980-0b55-48fc-967c-7597d305385d'	System	09 Aug 2020 06:49:43
User entered 'None (0)'	System	09 Aug 2020 06:49:43

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-09T00:49:34', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '5d26f980-0b55-48fc-967c-7597d305385d'	System	09 Aug 2020 06:49:43
User entered 'None (0)'	System	09 Aug 2020 06:49:43

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-09T00:49:37', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '5d26f980-0b55-48fc-967c-7597d305385d'	System	09 Aug 2020 06:49:43
User entered 'No (N)'	System	09 Aug 2020 06:49:43

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-09T00:49:40', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '5d26f980-0b55-48fc-967c-7597d305385d'	System	09 Aug 2020 06:49:43
User entered '09 Aug 2020 00:49'	System	09 Aug 2020 06:49:43

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 7'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-10T00:20:54', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '515ba18d-8425-4911-be86-56111869b262'	System	10 Aug 2020 06:21:55
User entered 'None (0)'	System	10 Aug 2020 06:21:55

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-10T00:20:56', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '515ba18d-8425-4911-be86-56111869b262'	System	10 Aug 2020 06:21:55
User entered 'None (0)'	System	10 Aug 2020 06:21:55

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-10T00:20:58', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '515ba18d-8425-4911-be86-56111869b262'	System	10 Aug 2020 06:21:55
User entered 'None (0)'	System	10 Aug 2020 06:21:55

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-10T00:21:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '515ba18d-8425-4911-be86-56111869b262'	System	10 Aug 2020 06:21:55
User entered 'None (0)'	System	10 Aug 2020 06:21:55

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US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-10T00:21:01', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '515ba18d-8425-4911-be86-56111869b262'	System	10 Aug 2020 06:21:55
User entered 'None (0)'	System	10 Aug 2020 06:21:55

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-10T00:21:03', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '515ba18d-8425-4911-be86-56111869b262'	System	10 Aug 2020 06:21:55
User entered 'None (0)'	System	10 Aug 2020 06:21:55

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-10T00:21:06', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '515ba18d-8425-4911-be86-56111869b262'	System	10 Aug 2020 06:21:55
User entered 'No (N)'	System	10 Aug 2020 06:21:55

FDA-CBER-2022-1614-0082791

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-08-10T00:21:09', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '515ba18d-8425-4911-be86-56111869b262'	System	10 Aug 2020 06:21:55
User entered '10 Aug 2020 00:21'	System	10 Aug 2020 06:21:55

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 16:30:51

US3142056
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 16:30:51

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US3142056
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jill York (b) (4)	20 Oct 2020 20:10:47

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US3142056
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '10 Aug 2020'	Jill York (b) (4)	20 Oct 2020 20:10:47

US3142056
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	20 Oct 2020 20:10:47

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US3142056
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Jill York (b) (4)	20 Oct 2020 20:10:47

US3142056
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	05 Oct 2020 20:52:45

US3142056
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered '1'	System	05 Oct 2020 20:52:45

US3142056
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jill York (b) (4)	20 Oct 2020 20:11:07

US3142056
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '17 Aug 2020'	Jill York (b) (4)	20 Oct 2020 20:11:07

FDA-CBER-2022-1614-0082802

US3142056
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	20 Oct 2020 20:11:07

FDA-CBER-2022-1614-0082803

US3142056
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Jill York (b) (4)	20 Oct 2020 20:11:07

FDA-CBER-2022-1614-0082804

US3142056
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	05 Oct 2020 20:52:50

US3142056
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered '1'	System	05 Oct 2020 20:52:50

US3142056
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jill York (b) (4)	20 Oct 2020 20:11:34

US3142056
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered '24 Aug 2020'	Jill York (b) (4)	20 Oct 2020 20:11:34

US3142056
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	20 Oct 2020 20:11:34

US3142056
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Jill York (b) (4)	20 Oct 2020 20:11:34

FDA-CBER-2022-1614-0082810

US3142056
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	05 Oct 2020 20:52:56

US3142056
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered '1'	System	05 Oct 2020 20:52:56

US3142056
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jill York (b) (4)	20 Oct 2020 21:55:37

US3142056
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '1 Sep 2020'	Jill York (b) (4)	20 Oct 2020 21:55:37

US3142056
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'Clinic (Clinic)'	Jill York (b) (4)	20 Oct 2020 21:55:37

US3142056
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered 'VISIT2'	System	20 Oct 2020 21:55:37

FDA-CBER-2022-1614-0082816

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User accepted default value 'Pre-Dose (PREDOSE)'	Jill York (b) (4)	20 Oct 2020 21:57:25

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jill York (b) (4)	20 Oct 2020 21:57:25

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered '1 Sep 2020'	Jill York (b) (4)	20 Oct 2020 21:57:25

FDA-CBER-2022-1614-0082819

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered '07:58'	(b) (4) Jill York (b) (4)	20 Oct 2020 21:57:25

FDA-CBER-2022-1614-0082820

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered '1 Sep 2020 07:58'	System	20 Oct 2020 21:57:25

FDA-CBER-2022-1614-0082821

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '97.3' F	Jill York (b) (4)	20 Oct 2020 21:57:25

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Other (Other)'	Jill York (b) (4)	20 Oct 2020 21:57:25

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'temporal'	Jill York (b) (4)	20 Oct 2020 21:57:25

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '63'	Jill York (b) (4)	20 Oct 2020 21:57:25

FDA-CBER-2022-1614-0082825

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered 'bpm'	System	20 Oct 2020 21:57:25

FDA-CBER-2022-1614-0082826

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered '15'	Jill York (b) (4)	20 Oct 2020 21:57:25

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered 'breaths/min'	System	20 Oct 2020 21:57:25

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered '122'	Jill York (b) (4)	20 Oct 2020 21:57:25

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered 'mmHg'	System	20 Oct 2020 21:57:25

FDA-CBER-2022-1614-0082830

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '84'	Jill York (b) (4)	20 Oct 2020 21:57:25

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered 'mmHg'	System	20 Oct 2020 21:57:25

FDA-CBER-2022-1614-0082832

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User accepted default value 'Post-Dose (POSTDOSE)'	Jill York (b) (4)	20 Oct 2020 21:57:25

FDA-CBER-2022-1614-0082833

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jill York (b) (4)	20 Oct 2020 21:57:25

FDA-CBER-2022-1614-0082834

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered '1 Sep 2020'	Jill York (b) (4)	20 Oct 2020 21:57:25

FDA-CBER-2022-1614-0082835

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered '08:53'	(b) (4) Jill York (b) (4)	20 Oct 2020 21:57:25

FDA-CBER-2022-1614-0082836

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered '1 Sep 2020 08:53'	System	20 Oct 2020 21:57:25

FDA-CBER-2022-1614-0082837

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	24 Oct 2020 12:38:00
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'not an AE not CS' (Site from System).	Jill York (b) (4)	20 Oct 2020 21:57:40
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	20 Oct 2020 21:57:25
User entered '96.6' F	Jill York (b) (4)	20 Oct 2020 21:57:25

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'Other (Other)'	Jill York (b) (4)	20 Oct 2020 21:57:25

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'temporal'	Jill York (b) (4)	20 Oct 2020 21:57:25

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered '59'	(b) (4) Jill York (b) (4)	20 Oct 2020 21:57:25

FDA-CBER-2022-1614-0082841

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered 'bpm'	System	20 Oct 2020 21:57:25

FDA-CBER-2022-1614-0082842

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered '14'	Jill York (b) (4)	20 Oct 2020 21:57:25

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered 'breaths/min'	System	20 Oct 2020 21:57:25

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered '139'	Jill York (b) (4)	20 Oct 2020 21:57:25

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered 'mmHg'	System	20 Oct 2020 21:57:25

FDA-CBER-2022-1614-0082846

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '74'	Jill York (b) (4)	20 Oct 2020 21:57:25

US3142056
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered 'mmHg'	System	20 Oct 2020 21:57:25

FDA-CBER-2022-1614-0082848

US3142056
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jill York (b) (4)	20 Oct 2020 21:57:52

US3142056
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered '1 Sep 2020'	Jill York (b) (4)	20 Oct 2020 21:57:52

FDA-CBER-2022-1614-0082850

US3142056
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	05 Oct 2020 20:53:22

US3142056
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	05 Oct 2020 20:53:22

US3142056
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
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)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	05 Oct 2020 20:53:22

US3142056
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered 'MRNA-1273 OR PLACEBO'	System	05 Oct 2020 20:53:22

US3142056
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 15:26:43
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	21 Oct 2020 15:26:43
User entered '1 Sep 2020' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	21 Oct 2020 15:26:43
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	20 Oct 2020 21:55:37
User entered '05 Oct 2020'	Shelby Pickle (b) (4) (b) (4)	05 Oct 2020 20:53:22

US3142056
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '14:45'	Shelby Pickle (b) (4) (b) (4)	05 Oct 2020 20:53:22

US3142056
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered '1 Sep 2020 14:45'	System	21 Oct 2020 15:26:43
User entered '05 Oct 2020 14:45'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0082857

US3142056
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Left Arm (LEFT ARM)'	Shelby Pickle (b) (4) (b) (4)	05 Oct 2020 20:53:22

US3142056
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered 'ONCE'	System	05 Oct 2020 20:53:22

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US3142056
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered 'INTRAMUSCULAR'	System	05 Oct 2020 20:53:22

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US3142056
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:00:27
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jill York (b) (4)	20 Oct 2020 21:58:16

FDA-CBER-2022-1614-0082861

US3142056
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:00:27
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 01SEP2020, however this date is presently recorded for Visit 2 Day 29. Please clarify if the Unscheduled sample collected on 01SEP2020 is actually for Visit 2 Day 29 and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 09:22:32
Query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 01SEP2020, however this date is presently recorded for Visit 2 Day 29. Please clarify if the Unscheduled sample collected on 01SEP2020 is actually for Visit 2 Day 29 and update as appropriate.' answered with 'Information is correct. Unscheduled lab kit was used for this visit due to lack of supplies ' (Site from DM).	Meghan York (b) (4) (b) (4)	27 Oct 2020 19:15:14
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 01SEP2020, however this date is presently recorded for Visit 2 Day 29. Please clarify if the Unscheduled sample collected on 01SEP2020 is actually for Visit 2 Day 29 and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 02:48:50
User entered '1 Sep 2020'	Jill York (b) (4)	20 Oct 2020 21:58:16

FDA-CBER-2022-1614-0082862

US3142056
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:00:27
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '08:06'	Jill York (b) (4)	20 Oct 2020 21:58:16

FDA-CBER-2022-1614-0082863

US3142056
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:00:27
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered '1 Sep 2020 08:06'	System	20 Oct 2020 21:58:16

FDA-CBER-2022-1614-0082864

US3142056
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 11 Aug 2021 22:00:27
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 01SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please review and confirm the Correct Visit and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 08:22:34
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 01SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please review and confirm the Correct Visit and update as appropriate. Else Clarify, Thank you.' answered with 'Unscheduled lab kit was used for this visit due to lack of supplies. ' (Site from DM).	Meghan York (b) (4) (b) (4)	23 Oct 2020 15:09:16
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 01SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please review and confirm the Correct Visit and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 23:31:29
User entered '1 Sep 2020'	Jill York (b) (4)	20 Oct 2020 21:58:32

FDA-CBER-2022-1614-0082865

US3142056
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:00:27
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jill York (b) (4)	20 Oct 2020 21:58:32

FDA-CBER-2022-1614-0082866

US3142056
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:00:27
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jill York (b) (4)	20 Oct 2020 21:58:32

FDA-CBER-2022-1614-0082867

US3142056
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:00:27
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered '08:07'	Jill York (b) (4)	20 Oct 2020 21:58:32

FDA-CBER-2022-1614-0082868

US3142056
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:00:27
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered '1 Sep 2020 08:07'	System	20 Oct 2020 21:58:32

FDA-CBER-2022-1614-0082869

US3142056
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:00:27
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jill York (b) (4)	20 Oct 2020 21:58:32

FDA-CBER-2022-1614-0082870

US3142056
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:00:27
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	Jill York (b) (4)	20 Oct 2020 21:58:32

US3142056
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:00:27
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Jill York (b) (4)	20 Oct 2020 21:58:32

FDA-CBER-2022-1614-0082872

US3142056
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:00:27
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered empty.	System	20 Oct 2020 21:58:32

FDA-CBER-2022-1614-0082873

US3142056
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jill York (b) (4)	20 Oct 2020 20:14:55

FDA-CBER-2022-1614-0082874

US3142056
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered '1'	System	20 Oct 2020 20:14:55

FDA-CBER-2022-1614-0082875

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082877

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082878

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082882

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '01 Sep 2020 15:05'	System	21 Oct 2020 15:26:43
User entered '05 Oct 2020 15:05'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '01 Sep 2020 17:35'	System	21 Oct 2020 15:26:43
User entered '05 Oct 2020 17:35'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082886

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082887

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082891

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '01 Sep 2020 18:30'	System	21 Oct 2020 15:26:43
User entered '05 Oct 2020 18:30'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '02 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 2'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:00:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082895

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:00:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082896

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:00:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082897

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:00:27
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082898

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:00:27
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082900

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '02 Sep 2020 12:00'	System	21 Oct 2020 15:26:43
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '03 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 3'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:00:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082904

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:00:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082905

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:00:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:00:27
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082907

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:00:27
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082909

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '03 Sep 2020 12:00'	System	21 Oct 2020 15:26:43
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '04 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 4'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0082912

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:00:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082913

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:00:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082914

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:00:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:00:27
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082916

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:00:27
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082917

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082918

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '04 Sep 2020 12:00'	System	21 Oct 2020 15:26:43
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0082919

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '05 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 5'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0082921

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:00:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082922

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:00:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082923

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:00:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:00:27
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082925

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:00:27
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082926

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082927

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '05 Sep 2020 12:00'	System	21 Oct 2020 15:26:43
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '06 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 6'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0082930

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:00:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082931

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:00:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082932

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:00:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:00:27
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:00:27
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082936

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '06 Sep 2020 12:00'	System	21 Oct 2020 15:26:43
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0082937

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '07 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 7'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0082939

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:00:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082940

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:00:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082941

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:00:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:00:27
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:00:27
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082944

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082945

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '07 Sep 2020 12:00'	System	21 Oct 2020 15:26:43
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0082946

US3142056
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '08 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0082947

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0082949

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082950

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0082951

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0082953

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0082954

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082955

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '01 Sep 2020 15:05'	System	21 Oct 2020 15:26:43
User entered '05 Oct 2020 15:05'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0082956

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '01 Sep 2020 17:35'	System	21 Oct 2020 15:26:43
User entered '05 Oct 2020 17:35'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0082957

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0082959

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082960

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0082961

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082962

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0082963

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0082964

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082965

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '01 Sep 2020 18:30'	System	21 Oct 2020 15:26:43
User entered '05 Oct 2020 18:30'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0082966

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '02 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0082967

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 2'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0082968

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0082969

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:00:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082970

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:00:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082972

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0082973

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0082974

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082975

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '02 Sep 2020 12:00'	System	21 Oct 2020 15:26:43
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '03 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0082977

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 3'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0082978

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:00:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0082981

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:00:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082982

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0082983

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0082984

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082985

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '03 Sep 2020 12:00'	System	21 Oct 2020 15:26:43
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '04 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 4'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0082989

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:00:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0082991

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:00:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0082993

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0082994

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0082995

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '04 Sep 2020 12:00'	System	21 Oct 2020 15:26:43
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '05 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 5'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0082998

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:00:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0083001

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:00:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0083003

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0083004

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083005

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '05 Sep 2020 12:00'	System	21 Oct 2020 15:26:43
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '06 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0083007

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 6'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0083009

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:00:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:00:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0083013

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0083014

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083015

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '06 Sep 2020 12:00'	System	21 Oct 2020 15:26:43
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '07 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 7'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0083019

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:00:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083020

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0083021

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:00:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0083023

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

FDA-CBER-2022-1614-0083024

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:00:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083025

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '07 Sep 2020 12:00'	System	21 Oct 2020 15:26:43
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '08 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083029

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083030

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083031

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083033

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083034

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083036

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '01 Sep 2020 15:05'	System	21 Oct 2020 15:26:43
User entered '05 Oct 2020 15:05'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '01 Sep 2020 17:35'	System	21 Oct 2020 15:26:43
User entered '05 Oct 2020 17:35'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083040

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083041

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083042

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083044

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083045

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083047

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '01 Sep 2020 18:30'	System	21 Oct 2020 15:26:43
User entered '05 Oct 2020 18:30'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '02 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 2'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083051

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083052

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083053

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083055

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083056

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083058

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '02 Sep 2020 12:00'	System	21 Oct 2020 15:26:43
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '03 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 3'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0083061

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083062

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083063

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083064

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083066

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083067

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083069

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '03 Sep 2020 12:00'	System	21 Oct 2020 15:26:43
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '04 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 4'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083073

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083074

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083075

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083077

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083078

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083080

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '04 Sep 2020 12:00'	System	21 Oct 2020 15:26:43
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '05 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 5'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083084

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083085

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083086

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083089

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083091

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '05 Sep 2020 12:00'	System	21 Oct 2020 15:26:43
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '06 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0083093

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 6'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083095

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083096

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083099

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083100

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083102

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '06 Sep 2020 12:00'	System	21 Oct 2020 15:26:43
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 20:53:22

FDA-CBER-2022-1614-0083103

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '07 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	05 Oct 2020 20:53:22
User entered 'Day 7'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083106

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083107

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083108

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083111

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
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 01:28:29

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29

FDA-CBER-2022-1614-0083113

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '07 Sep 2020 12:00'	System	21 Oct 2020 15:26:43
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 20:53:22

US3142056
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:00:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
User entered '08 Sep 2020 11:59'	System	21 Oct 2020 15:26:43
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 20:53:22

US3142056
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4) Jill York (b) (4)	20 Oct 2020 20:15:29

FDA-CBER-2022-1614-0083116

US3142056
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	24 Oct 2020 12:23:44
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'date is within window' (Site from System).	Jill York (b) (4)	20 Oct 2020 20:15:51
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	20 Oct 2020 20:15:29
User entered '8 Sep 2020'	Jill York (b) (4)	20 Oct 2020 20:15:29

US3142056
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	20 Oct 2020 20:15:29

US3142056
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Jill York (b) (4)	20 Oct 2020 20:15:29

US3142056
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jill York (b) (4)	20 Oct 2020 20:15:58

US3142056
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered '1'	System	20 Oct 2020 20:15:58

US3142056
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4) Jill York (b) (4)	20 Oct 2020 20:16:33

US3142056
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 06:55:57
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with '.' (Site from System).	Jill York (b) (4)	20 Oct 2020 20:19:12
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	20 Oct 2020 20:16:33
User entered '17 Sep 2020'	Jill York (b) (4)	20 Oct 2020 20:16:33

US3142056
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	20 Oct 2020 20:16:33

US3142056
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Jill York (b) (4)	20 Oct 2020 20:16:33

US3142056
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jill York (b) (4)	20 Oct 2020 20:16:39

US3142056
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered '1'	System	20 Oct 2020 20:16:39

US3142056
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4) Jill York (b) (4)	20 Oct 2020 20:17:00

US3142056
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
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)	27 Oct 2020 06:57:53
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 '.' (Site from System).	Jill York (b) (4)	20 Oct 2020 20:17:07
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	20 Oct 2020 20:17:00
User entered '22 Sep 2020'	Jill York (b) (4)	20 Oct 2020 20:17:00

US3142056
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	20 Oct 2020 20:17:00

US3142056
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Jill York (b) (4)	20 Oct 2020 20:17:00

US3142056
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jill York (b) (4)	20 Oct 2020 20:17:13

US3142056
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered '1'	System	20 Oct 2020 20:17:13

FDA-CBER-2022-1614-0083133

US3142056
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:55:58
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 11 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).		26 Apr 2021 12:12:27
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 11 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'Labs have been completed for Subject. However, Source cannot comply with data to backup visit on 11NOV2020. Phone visit on 10NOV2020 eludes to visit on the 11NOV2020, However, no Source is in subjects binder' (Site from DM).	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 20:17:18
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 11 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 05:07:57
Query 'Per GCL Lab Recon: GCL is reporting receiving a COVID PCR Swab dated 01Sep2020, however, no COVID-19 Assessment Contact, Symptom Log, Diagnostic test, or Illness visit has been completed matching this date. Please reconcile.' canceled (Site from DM).		24 Oct 2020 23:53:41

US3142056
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was this visit performed?

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Recon: GCL is reporting receiving a COVID PCR Swab dated 01Sep2020, however, no COVID-19 Assessment Contact, Symptom Log, Diagnostic test, or Illness visit has been completed matching this date. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 02:40:57
User entered 'Yes (Y)'	Jill York (b) (4)	20 Oct 2020 21:58:59

US3142056
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:55:58
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 21 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 06:17:24
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 21 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).		29 Dec 2020 06:54:34
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).		24 Oct 2020 12:40:25
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'what? no, this in another incorrect query' (Site from System).	Jill York (b) (4)	20 Oct 2020 21:59:40
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	20 Oct 2020 21:58:59
User entered '29 Sep 2020'	Jill York (b) (4)	20 Oct 2020 21:58:59

US3142056
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:55:58
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 28 JAN 2021 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 06:17:29
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 28 JAN 2021 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).		19 Feb 2021 07:26:12
User entered 'Clinic (Clinic)'	Jill York (b) (4)	20 Oct 2020 21:58:59

US3142056
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:55:58
User entered 'VISIT3'	System	20 Oct 2020 21:58:59

FDA-CBER-2022-1614-0083138

US3142056
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 22:00:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 22:00:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Jill York (b) (4)	20 Oct 2020 22:00:46
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 22:00:34
User entered empty.	Jill York (b) (4)	20 Oct 2020 22:00:34

US3142056
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '29 Sep 2020'	Jill York (b) (4)	20 Oct 2020 22:00:34

FDA-CBER-2022-1614-0083140

US3142056
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered '08:18'	(b) (4) Jill York (b) (4)	20 Oct 2020 22:00:34

FDA-CBER-2022-1614-0083141

US3142056
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered '29 Sep 2020 08:18'	System	20 Oct 2020 22:00:34

FDA-CBER-2022-1614-0083142

US3142056
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	24 Oct 2020 12:37:40
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'not an AE' (Site from System).	Jill York (b) (4)	20 Oct 2020 22:00:54
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	20 Oct 2020 22:00:34
User entered '96.2' F	Jill York (b) (4)	20 Oct 2020 22:00:34

US3142056
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Other (Other)'	Jill York (b) (4)	20 Oct 2020 22:00:34

US3142056
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'temporal'	Jill York (b) (4)	20 Oct 2020 22:00:34

FDA-CBER-2022-1614-0083145

US3142056
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '61'	Jill York (b) (4)	20 Oct 2020 22:00:34

FDA-CBER-2022-1614-0083146

US3142056
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered 'bpm'	System	20 Oct 2020 22:00:34

FDA-CBER-2022-1614-0083147

US3142056
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered '12'	(b) (4) Jill York (b) (4)	20 Oct 2020 22:00:34

FDA-CBER-2022-1614-0083148

US3142056
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered 'breaths/min'	System	20 Oct 2020 22:00:34

FDA-CBER-2022-1614-0083149

US3142056
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '126'	Jill York (b) (4)	20 Oct 2020 22:00:34

FDA-CBER-2022-1614-0083150

US3142056
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered 'mmHg'	System	20 Oct 2020 22:00:34

FDA-CBER-2022-1614-0083151

US3142056
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '75'	Jill York (b) (4)	20 Oct 2020 22:00:34

FDA-CBER-2022-1614-0083152

US3142056
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered 'mmHg'	System	20 Oct 2020 22:00:34

FDA-CBER-2022-1614-0083153

US3142056
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35

FDA-CBER-2022-1614-0083154

US3142056
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35

FDA-CBER-2022-1614-0083155

US3142056
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jill York (b) (4)	20 Oct 2020 22:01:04

US3142056
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '29 Sep 2020'	Jill York (b) (4)	20 Oct 2020 22:01:04

FDA-CBER-2022-1614-0083157

US3142056
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:00:27
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jill York (b) (4)	20 Oct 2020 22:01:21

US3142056
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:00:27
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '29 Sep 2020'	Jill York (b) (4)	20 Oct 2020 22:01:21

US3142056
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:00:27
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered '08:25'	Jill York (b) (4)	20 Oct 2020 22:01:21

US3142056
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:00:27
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered '29 Sep 2020 08:25'	System	20 Oct 2020 22:01:21

US3142056
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
Data hard locked.	(b) (4) (b) (4), (b) (6)	24 Apr 2021 06:12:35
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 28 sample with Accession # 1F651168876 is reported with 28JAN2021 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you.' (Site from DM).		22 Apr 2021 05:34:57
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 28 sample with Accession # 1F651168876 is reported with 28JAN2021 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you.' answered with 'data has been entered on Convalescence Visit Day 28 on 28 Jan 2021' (Site from DM).	Jill York (b) (4)	21 Apr 2021 15:08:23
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 28 sample with Accession # 1F651168876 is reported with 28JAN2021 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 07:31:46
User entered 'Yes (Y)'	Jill York (b) (4)	20 Oct 2020 22:01:27

US3142056
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:35
User entered '1'	System	20 Oct 2020 22:01:27

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 64'	System	03 Aug 2020 16:30:51

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15
Data entry locked.	System	03 Aug 2020 16:30:51
User entered '03 Oct 2020 00:01'	System	03 Aug 2020 16:30:51

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15
Data entry locked.	System	03 Aug 2020 16:30:51
User entered '07 Oct 2020 23:59'	System	03 Aug 2020 16:30:51

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 71'	System	03 Aug 2020 16:30:51

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15
Data entry locked.	System	03 Aug 2020 16:30:51
User entered '10 Oct 2020 00:01'	System	03 Aug 2020 16:30:51

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:41:15
Data entry locked.	System	03 Aug 2020 16:30:51
User entered '14 Oct 2020 23:59'	System	03 Aug 2020 16:30:51

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 78'	System	03 Aug 2020 16:30:51

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-10-20T01:34:23', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'bf5edec2-1ee6-4447-aca0-6241783b18aa'	System	20 Oct 2020 07:34:43
User entered 'No (N)'	System	20 Oct 2020 07:34:43

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-10-20T01:34:27', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'bf5edec2-1ee6-4447-aca0-6241783b18aa'	System	20 Oct 2020 07:34:43
User entered 'No (N)'	System	20 Oct 2020 07:34:43

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-10-20T01:34:36', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'bf5edec2-1ee6-4447-aca0-6241783b18aa'	System	20 Oct 2020 07:34:43
User entered '20 Oct 2020 01:34:36'	System	20 Oct 2020 07:34:43

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered '17 Oct 2020 00:01'	System	03 Aug 2020 16:30:51

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered '21 Oct 2020 23:59'	System	03 Aug 2020 16:30:51

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 92'	System	03 Aug 2020 16:30:51

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-10-31T00:02:02', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '8fbd7dde-0773-4341-be3f-5453982582a0'	System	31 Oct 2020 06:02:35
User entered 'No (N)'	System	31 Oct 2020 06:02:35

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-10-31T00:02:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '8fbd7dde-0773-4341-be3f-5453982582a0'	System	31 Oct 2020 06:02:35
User entered 'No (N)'	System	31 Oct 2020 06:02:35

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-10-31T00:02:33', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '8fbd7dde-0773-4341-be3f-5453982582a0'	System	31 Oct 2020 06:02:35
User entered '31 Oct 2020 00:02:33'	System	31 Oct 2020 06:02:35

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered '31 Oct 2020 00:01'	System	03 Aug 2020 16:30:51

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered '04 Nov 2020 23:59'	System	03 Aug 2020 16:30:51

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 99'	System	03 Aug 2020 16:30:51

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-09T02:55:07', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'd3ab2798-63d9-43e0-a208-5033cf8abae8'	System	09 Nov 2020 09:55:28
User entered 'No (N)'	System	09 Nov 2020 09:55:28

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-09T02:55:16', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'd3ab2798-63d9-43e0-a208-5033cf8abae8'	System	09 Nov 2020 09:55:28
User entered 'No (N)'	System	09 Nov 2020 09:55:28

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-09T02:55:24', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'd3ab2798-63d9-43e0-a208-5033cf8abae8'	System	09 Nov 2020 09:55:28
User entered '09 Nov 2020 02:55:24'	System	09 Nov 2020 09:55:28

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered '07 Nov 2020 00:01'	System	03 Aug 2020 16:30:51

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered '11 Nov 2020 23:59'	System	03 Aug 2020 16:30:51

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered 'Day 106'	System	03 Aug 2020 16:30:51

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US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered 'Yes (Y)'	System	15 Nov 2020 08:11:18

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:28', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered 'No (N)'	System	15 Nov 2020 08:11:18

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:33', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered 'Yes (Y)'	System	15 Nov 2020 08:11:18

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:46', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered '0'	System	15 Nov 2020 08:11:18

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US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:46', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered '0'	System	15 Nov 2020 08:11:18

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:46', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered '1'	System	15 Nov 2020 08:11:18

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:46', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered '0'	System	15 Nov 2020 08:11:18

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:46', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered '0'	System	15 Nov 2020 08:11:18

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:46', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered '0'	System	15 Nov 2020 08:11:18

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:46', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered '0'	System	15 Nov 2020 08:11:18

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:46', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered '0'	System	15 Nov 2020 08:11:18

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:46', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered '0'	System	15 Nov 2020 08:11:18

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:46', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered '0'	System	15 Nov 2020 08:11:18

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:46', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered '0'	System	15 Nov 2020 08:11:18

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US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:46', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered '1'	System	15 Nov 2020 08:11:18

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:46', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered '1'	System	15 Nov 2020 08:11:18

FDA-CBER-2022-1614-0083254

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:46', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered '1'	System	15 Nov 2020 08:11:18

FDA-CBER-2022-1614-0083255

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:46', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered '0'	System	15 Nov 2020 08:11:18

FDA-CBER-2022-1614-0083256

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:46', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered '0'	System	15 Nov 2020 08:11:18

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:46', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered '0'	System	15 Nov 2020 08:11:18

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Please 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)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:53', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Nov 2020 08:11:18

US3142056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:10:58', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered 'No (N)'	System	15 Nov 2020 08:11:18

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-15T01:11:08', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6faf3f8a-b649-4d34-abcc-4e663a537fc0'	System	15 Nov 2020 08:11:18
User entered '15 Nov 2020 01:11:08'	System	15 Nov 2020 08:11:18

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered '14 Nov 2020 00:01'	System	03 Aug 2020 16:30:51

US3142056
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:28:29
Data entry locked.	System	03 Aug 2020 16:30:51
User entered '18 Nov 2020 23:59'	System	03 Aug 2020 16:30:51

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:41:15

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2020-11-20T13:54:44', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6b846358-895d-4d29-a10f-dddb3229e522'	System	20 Nov 2020 20:54:54
User entered 'No (N)'	System	20 Nov 2020 20:54:54

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 (d12b6ebc97b6e00f)', Time: '2020-11-20T13:54:47', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6b846358-895d-4d29-a10f-dddb3229e522'	System	20 Nov 2020 20:54:54
User entered 'No (N)'	System	20 Nov 2020 20:54:54

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-20T13:54:51', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '6b846358-895d-4d29-a10f-dddb3229e522'	System	20 Nov 2020 20:54:54
User entered '20 Nov 2020 13:54:51'	System	20 Nov 2020 20:54:54

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:41:15

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2020-11-25T05:46:13', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'c52d833d-da74-4008-9fdf-dcb24090d0f9'	System	25 Nov 2020 12:46:32
User entered 'No (N)'	System	25 Nov 2020 12:46:32

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 (d12b6ebc97b6e00f)', Time: '2020-11-25T05:46:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'c52d833d-da74-4008-9fdf-dcb24090d0f9'	System	25 Nov 2020 12:46:32
User entered 'No (N)'	System	25 Nov 2020 12:46:32

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-11-25T05:46:29', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'c52d833d-da74-4008-9fdf-dcb24090d0f9'	System	25 Nov 2020 12:46:32
User entered '25 Nov 2020 05:46:29'	System	25 Nov 2020 12:46:32

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:41:15

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2020-12-05T09:20:22', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '44c7c530-c41e-41c3-aeb1-ba052e8af6b4'	System	05 Dec 2020 16:20:30
User entered 'No (N)'	System	05 Dec 2020 16:20:30

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 (d12b6ebc97b6e00f)', Time: '2020-12-05T09:20:25', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '44c7c530-c41e-41c3-aeb1-ba052e8af6b4'	System	05 Dec 2020 16:20:30
User entered 'No (N)'	System	05 Dec 2020 16:20:30

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-05T09:20:27', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '44c7c530-c41e-41c3-aeb1-ba052e8af6b4'	System	05 Dec 2020 16:20:30
User entered '05 Dec 2020 09:20:27'	System	05 Dec 2020 16:20:30

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:41:15

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2020-12-18T07:01:42', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered 'Yes (Y)'	System	18 Dec 2020 14:02:48

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 (d12b6ebc97b6e00f)', Time: '2020-12-18T07:01:49', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered 'No (N)'	System	18 Dec 2020 14:02:48

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2020-12-18T07:01:55', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered 'Yes (Y)'	System	18 Dec 2020 14:02:48

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-18T07:02:17', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered '0'	System	18 Dec 2020 14:02:48

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-18T07:02:17', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered '0'	System	18 Dec 2020 14:02:48

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-18T07:02:17', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered '1'	System	18 Dec 2020 14:02:48

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Shortness of breath

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-18T07:02:17', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered '0'	System	18 Dec 2020 14:02:48

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Difficulty breathing

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-18T07:02:17', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered '0'	System	18 Dec 2020 14:02:48

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-18T07:02:17', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered '1'	System	18 Dec 2020 14:02:48

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Muscle aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-18T07:02:17', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered '1'	System	18 Dec 2020 14:02:48

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Body aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-18T07:02:17', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered '0'	System	18 Dec 2020 14:02:48

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-18T07:02:17', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered '1'	System	18 Dec 2020 14:02:48

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
New loss of taste

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-18T07:02:17', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered '0'	System	18 Dec 2020 14:02:48

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
New loss of smell

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-18T07:02:17', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered '0'	System	18 Dec 2020 14:02:48

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Sore throat

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-18T07:02:17', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered '0'	System	18 Dec 2020 14:02:48

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Congestion

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-18T07:02:17', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered '0'	System	18 Dec 2020 14:02:48

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Runny nose

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-18T07:02:17', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered '1'	System	18 Dec 2020 14:02:48

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-18T07:02:17', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered '0'	System	18 Dec 2020 14:02:48

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-18T07:02:17', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered '0'	System	18 Dec 2020 14:02:48

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-18T07:02:17', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered '0'	System	18 Dec 2020 14:02:48

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Please 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 (d12b6ebc97b6e00f)', Time: '2020-12-18T07:02:27', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Dec 2020 14:02:48

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2020-12-18T07:02:31', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered 'No (N)'	System	18 Dec 2020 14:02:48

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-18T07:02:39', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ccbd7cbc-192f-4d12-91ae-fdc418fcb29e'	System	18 Dec 2020 14:02:48
User entered '18 Dec 2020 07:02:39'	System	18 Dec 2020 14:02:48

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:41:15

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; Experienced any new COVID-19 symptoms since last questionnaire or study contact? and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 02:45:41
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; Experienced any new COVID-19 symptoms since last questionnaire or study contact? and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'AE now entered ' (Site from DM).	Jill York (b) (4)	26 Mar 2021 03:26:35
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; Experienced any new COVID-19 symptoms since last questionnaire or study contact? and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:23:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-23T06:39:29', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered 'Yes (Y)'	System	23 Dec 2020 13:41:31

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 (d12b6ebc97b6e00f)', Time: '2020-12-23T06:41:02', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered 'No (N)'	System	23 Dec 2020 13:41:31

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:09', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered 'Yes (Y)'	System	23 Dec 2020 13:41:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered '0'	System	23 Dec 2020 13:41:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered '0'	System	23 Dec 2020 13:41:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered '1'	System	23 Dec 2020 13:41:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Shortness of breath

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered '1'	System	23 Dec 2020 13:41:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Difficulty breathing

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered '1'	System	23 Dec 2020 13:41:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered '1'	System	23 Dec 2020 13:41:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Muscle aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered '1'	System	23 Dec 2020 13:41:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Body aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered '1'	System	23 Dec 2020 13:41:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered '1'	System	23 Dec 2020 13:41:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
New loss of taste

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered '0'	System	23 Dec 2020 13:41:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
New loss of smell

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered '0'	System	23 Dec 2020 13:41:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Sore throat

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered '1'	System	23 Dec 2020 13:41:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Congestion

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered '0'	System	23 Dec 2020 13:41:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Runny nose

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered '1'	System	23 Dec 2020 13:41:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered '0'	System	23 Dec 2020 13:41:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered '0'	System	23 Dec 2020 13:41:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered '0'	System	23 Dec 2020 13:41:31

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Please 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 (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:44', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Dec 2020 13:41:31

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:50', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered 'Yes (Y)'	System	23 Dec 2020 13:41:31

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Please 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 (d12b6ebc97b6e00f)', Time: '2020-12-23T06:40:53', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Dec 2020 13:41:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-23T06:41:21', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '008f1c88-2893-4362-911d-2b07efefebde'	System	23 Dec 2020 13:41:31
User entered '23 Dec 2020 06:41:21'	System	23 Dec 2020 13:41:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:41:15

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2020-12-30T09:33:17', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '91908b0f-ab9d-44ad-bc84-5515e69019b4'	System	30 Dec 2020 16:33:27
User entered 'No (N)'	System	30 Dec 2020 16:33:27

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 (d12b6ebc97b6e00f)', Time: '2020-12-30T09:33:21', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '91908b0f-ab9d-44ad-bc84-5515e69019b4'	System	30 Dec 2020 16:33:27
User entered 'No (N)'	System	30 Dec 2020 16:33:27

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2020-12-30T09:33:24', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '91908b0f-ab9d-44ad-bc84-5515e69019b4'	System	30 Dec 2020 16:33:27
User entered '30 Dec 2020 09:33:24'	System	30 Dec 2020 16:33:27

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:41:15

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2021-01-09T07:43:30', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '3ee47e8c-0568-49d2-9654-e495f512c67d'	System	09 Jan 2021 14:43:43
User entered 'No (N)'	System	09 Jan 2021 14:43:43

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 (d12b6ebc97b6e00f)', Time: '2021-01-09T07:43:35', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '3ee47e8c-0568-49d2-9654-e495f512c67d'	System	09 Jan 2021 14:43:43
User entered 'No (N)'	System	09 Jan 2021 14:43:43

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-01-09T07:43:39', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '3ee47e8c-0568-49d2-9654-e495f512c67d'	System	09 Jan 2021 14:43:43
User entered '09 Jan 2021 07:43:39'	System	09 Jan 2021 14:43:43

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:41:15

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2021-01-16T04:42:15', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '3308c22b-5ad1-402b-b731-1446b7573b89'	System	16 Jan 2021 11:42:58
User entered 'No (N)'	System	16 Jan 2021 11:42:58

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 (d12b6ebc97b6e00f)', Time: '2021-01-16T04:42:21', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '3308c22b-5ad1-402b-b731-1446b7573b89'	System	16 Jan 2021 11:42:58
User entered 'No (N)'	System	16 Jan 2021 11:42:58

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-01-16T04:42:54', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '3308c22b-5ad1-402b-b731-1446b7573b89'	System	16 Jan 2021 11:42:58
User entered '16 Jan 2021 04:42:54'	System	16 Jan 2021 11:42:58

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:41:15

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2021-01-31T16:50:50', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered 'Yes (Y)'	System	31 Jan 2021 23:51:56

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 (d12b6ebc97b6e00f)', Time: '2021-01-31T16:50:55', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered 'No (N)'	System	31 Jan 2021 23:51:56

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:02', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered 'Yes (Y)'	System	31 Jan 2021 23:51:56

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered '0'	System	31 Jan 2021 23:51:56

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered '0'	System	31 Jan 2021 23:51:56

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered '0'	System	31 Jan 2021 23:51:56

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Shortness of breath

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered '0'	System	31 Jan 2021 23:51:56

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Difficulty breathing

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered '0'	System	31 Jan 2021 23:51:56

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered '0'	System	31 Jan 2021 23:51:56

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Muscle aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered '0'	System	31 Jan 2021 23:51:56

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Body aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered '0'	System	31 Jan 2021 23:51:56

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered '0'	System	31 Jan 2021 23:51:56

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
New loss of taste

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered '0'	System	31 Jan 2021 23:51:56

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
New loss of smell

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered '0'	System	31 Jan 2021 23:51:56

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Sore throat

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered '1'	System	31 Jan 2021 23:51:56

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Congestion

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered '1'	System	31 Jan 2021 23:51:56

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Runny nose

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered '1'	System	31 Jan 2021 23:51:56

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered '0'	System	31 Jan 2021 23:51:56

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered '0'	System	31 Jan 2021 23:51:56

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:20', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered '0'	System	31 Jan 2021 23:51:56

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Please 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 (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:33', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Jan 2021 23:51:56

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:39', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered 'No (N)'	System	31 Jan 2021 23:51:56

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-01-31T16:51:45', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '466c5f33-de50-48fb-9dea-daf5a8f63e32'	System	31 Jan 2021 23:51:56
User entered '31 Jan 2021 16:51:45'	System	31 Jan 2021 23:51:56

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:41:15

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2021-02-06T00:49:19', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'd17909ae-f62a-4efe-b6a3-9049aa630cf7'	System	06 Feb 2021 07:49:31
User entered 'No (N)'	System	06 Feb 2021 07:49:31

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 (d12b6ebc97b6e00f)', Time: '2021-02-06T00:49:22', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'd17909ae-f62a-4efe-b6a3-9049aa630cf7'	System	06 Feb 2021 07:49:31
User entered 'No (N)'	System	06 Feb 2021 07:49:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-02-06T00:49:25', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'd17909ae-f62a-4efe-b6a3-9049aa630cf7'	System	06 Feb 2021 07:49:31
User entered '06 Feb 2021 00:49:25'	System	06 Feb 2021 07:49:31

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:41:15

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2021-02-19T04:32:54', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'e91384fa-ad32-4e9b-b236-9224265df8a9'	System	19 Feb 2021 11:33:07
User entered 'No (N)'	System	19 Feb 2021 11:33:07

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 (d12b6ebc97b6e00f)', Time: '2021-02-19T04:32:58', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'e91384fa-ad32-4e9b-b236-9224265df8a9'	System	19 Feb 2021 11:33:07
User entered 'No (N)'	System	19 Feb 2021 11:33:07

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-02-19T04:33:03', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'e91384fa-ad32-4e9b-b236-9224265df8a9'	System	19 Feb 2021 11:33:07
User entered '19 Feb 2021 04:33:03'	System	19 Feb 2021 11:33:07

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:41:15

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2021-02-24T00:37:09-07:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '7bdc4e45-3a70-4655-b2f6-f35680eb0a28'	System	24 Feb 2021 07:37:20
User entered 'No (N)'	System	24 Feb 2021 07:37:20

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 (d12b6ebc97b6e00f)', Time: '2021-02-24T00:37:12-07:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '7bdc4e45-3a70-4655-b2f6-f35680eb0a28'	System	24 Feb 2021 07:37:20
User entered 'No (N)'	System	24 Feb 2021 07:37:20

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-02-24T00:37:15-07:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '7bdc4e45-3a70-4655-b2f6-f35680eb0a28'	System	24 Feb 2021 07:37:20
User entered '24 Feb 2021 00:37:15'	System	24 Feb 2021 07:37:20

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:41:15

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2021-03-03T01:11:11-07:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '90ec27df-7305-4726-9681-38e40e0c3b38'	System	03 Mar 2021 08:11:27
User entered 'No (N)'	System	03 Mar 2021 08:11:27

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 (d12b6ebc97b6e00f)', Time: '2021-03-03T01:11:20-07:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '90ec27df-7305-4726-9681-38e40e0c3b38'	System	03 Mar 2021 08:11:27
User entered 'No (N)'	System	03 Mar 2021 08:11:27

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-03-03T01:11:24-07:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '90ec27df-7305-4726-9681-38e40e0c3b38'	System	03 Mar 2021 08:11:27
User entered '03 Mar 2021 01:11:24'	System	03 Mar 2021 08:11:27

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:41:15

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2021-03-10T23:51:46-07:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '16701c6e-4425-4878-aa42-85a8f77bb16b'	System	11 Mar 2021 06:51:57
User entered 'No (N)'	System	11 Mar 2021 06:51:57

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 (d12b6ebc97b6e00f)', Time: '2021-03-10T23:51:50-07:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '16701c6e-4425-4878-aa42-85a8f77bb16b'	System	11 Mar 2021 06:51:57
User entered 'No (N)'	System	11 Mar 2021 06:51:57

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-03-10T23:51:53-07:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '16701c6e-4425-4878-aa42-85a8f77bb16b'	System	11 Mar 2021 06:51:57
User entered '10 Mar 2021 23:51:53'	System	11 Mar 2021 06:51:57

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:41:15

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2021-03-18T04:26:07-06:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '1fc07d6e-6433-4186-83d2-8fb540170951'	System	18 Mar 2021 10:26:26
User entered 'No (N)'	System	18 Mar 2021 10:26:26

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 (d12b6ebc97b6e00f)', Time: '2021-03-18T04:26:10-06:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '1fc07d6e-6433-4186-83d2-8fb540170951'	System	18 Mar 2021 10:26:26
User entered 'No (N)'	System	18 Mar 2021 10:26:26

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-03-18T04:26:23-06:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '1fc07d6e-6433-4186-83d2-8fb540170951'	System	18 Mar 2021 10:26:26
User entered '18 Mar 2021 04:26:23'	System	18 Mar 2021 10:26:26

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:41:15

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2021-03-24T01:25:28-06:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '7e54a527-92be-44b9-962a-a7a75fd7e21e'	System	24 Mar 2021 07:25:43
User entered 'No (N)'	System	24 Mar 2021 07:25:43

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 (d12b6ebc97b6e00f)', Time: '2021-03-24T01:25:35-06:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '7e54a527-92be-44b9-962a-a7a75fd7e21e'	System	24 Mar 2021 07:25:43
User entered 'No (N)'	System	24 Mar 2021 07:25:43

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-03-24T01:25:39-06:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '7e54a527-92be-44b9-962a-a7a75fd7e21e'	System	24 Mar 2021 07:25:43
User entered '24 Mar 2021 01:25:39'	System	24 Mar 2021 07:25:43

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:41:15

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2021-03-31T10:27:51-06:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '4c30a362-312b-405d-8fe4-fcea98a0dfa9'	System	31 Mar 2021 16:28:09
User entered 'No (N)'	System	31 Mar 2021 16:28:09

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 (d12b6ebc97b6e00f)', Time: '2021-03-31T10:27:55-06:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '4c30a362-312b-405d-8fe4-fcea98a0dfa9'	System	31 Mar 2021 16:28:09
User entered 'No (N)'	System	31 Mar 2021 16:28:09

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-03-31T10:27:58-06:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '4c30a362-312b-405d-8fe4-fcea98a0dfa9'	System	31 Mar 2021 16:28:09
User entered '31 Mar 2021 10:27:58'	System	31 Mar 2021 16:28:09

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:41:15

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2021-04-08T09:28:57-06:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '55fe3537-4162-4976-9d32-db40c0ed8265'	System	08 Apr 2021 15:29:07
User entered 'No (N)'	System	08 Apr 2021 15:29:07

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 (d12b6ebc97b6e00f)', Time: '2021-04-08T09:28:59-06:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '55fe3537-4162-4976-9d32-db40c0ed8265'	System	08 Apr 2021 15:29:07
User entered 'No (N)'	System	08 Apr 2021 15:29:07

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-04-08T09:29:02-06:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '55fe3537-4162-4976-9d32-db40c0ed8265'	System	08 Apr 2021 15:29:07
User entered '08 Apr 2021 09:29:02'	System	08 Apr 2021 15:29:07

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:41:15

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2021-04-15T07:16:53-06:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'b2ffc550-732a-4bc1-b1a1-ec3d0160cb35'	System	15 Apr 2021 13:17:02
User entered 'No (N)'	System	15 Apr 2021 13:17:02

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 (d12b6ebc97b6e00f)', Time: '2021-04-15T07:16:55-06:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'b2ffc550-732a-4bc1-b1a1-ec3d0160cb35'	System	15 Apr 2021 13:17:02
User entered 'No (N)'	System	15 Apr 2021 13:17:02

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-04-15T07:16:58-06:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'b2ffc550-732a-4bc1-b1a1-ec3d0160cb35'	System	15 Apr 2021 13:17:02
User entered '15 Apr 2021 07:16:58'	System	15 Apr 2021 13:17:02

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:41:15

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

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 (d12b6ebc97b6e00f)', Time: '2021-04-24T06:39:08-06:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '14ba8de8-b0d7-4ac9-96ad-582d33c102df'	System	24 Apr 2021 12:39:23
User entered 'No (N)'	System	24 Apr 2021 12:39:23

US3142056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:27

Have you been exposed to someone with 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 (d12b6ebc97b6e00f)', Time: '2021-04-24T06:39:15-06:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '14ba8de8-b0d7-4ac9-96ad-582d33c102df'	System	24 Apr 2021 12:39:23
User entered 'No (N)'	System	24 Apr 2021 12:39:23

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-04-24T06:39:20-06:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: '14ba8de8-b0d7-4ac9-96ad-582d33c102df'	System	24 Apr 2021 12:39:23
User entered '24 Apr 2021 06:39:20'	System	24 Apr 2021 12:39:23

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 11:41:15

US3142056
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:00:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:15
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 11:41:15

US3142056

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:00:27

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)	24 Apr 2021 11:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-02-28T01:11:00-07:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ac97f315-c685-4d63-a59e-7a83902138e4'	System	28 Feb 2021 08:11:18
User entered 'No (N)'	System	28 Feb 2021 08:11:18

US3142056
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary (1)
Generated On: 11 Aug 2021 22:00:27
Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d12b6ebc97b6e00f)', Time: '2021-02-28T01:11:14-07:00', User OID: 'PatientReportedOutcome (US3142056)', ODM File OID: 'ac97f315-c685-4d63-a59e-7a83902138e4'	System	28 Feb 2021 08:11:18
User entered '28 Feb 2021 01:11:14'	System	28 Feb 2021 08:11:18

US3142056
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4) (b) (4)	27 Oct 2020 18:57:35

US3142056
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 11NOV2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review and update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 07:10:39
User opened query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 11NOV2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review and update the details under appropriate visit. Else clarify, thank you.' (Site from DM).		18 Nov 2020 06:58:20
User entered '27 Oct 2020'	Dalia Jeronimo (b) (4) (b) (4)	27 Oct 2020 18:57:35

FDA-CBER-2022-1614-0083685

US3142056
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4) (b) (4)	27 Oct 2020 18:57:35

US3142056
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Dalia Jeronimo (b) (4) (b) (4)	27 Oct 2020 18:57:35

US3142056
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4) (b) (4)	27 Oct 2020 18:57:12

US3142056
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:12:31
User entered '1'	System	27 Oct 2020 18:57:12

US3142056
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:49:47
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	30 Nov 2020 23:00:19

US3142056
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:49:47
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 11NOV2020 is reported under Illness Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 07:10:46
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 11NOV2020 is reported under Illness Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).		08 Dec 2020 12:17:30
User entered '30 Nov 2020'	Jami Wagner (b) (4) (b) (4)	30 Nov 2020 23:00:19

FDA-CBER-2022-1614-0083691

US3142056
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:49:47
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4) (b) (4)	30 Nov 2020 23:00:19

FDA-CBER-2022-1614-0083692

US3142056
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:49:47
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Jami Wagner (b) (4) (b) (4)	30 Nov 2020 23:00:19

FDA-CBER-2022-1614-0083693

US3142056
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:49:47
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	30 Nov 2020 23:00:25

US3142056
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:49:47
User entered '1'	System	30 Nov 2020 23:00:25

FDA-CBER-2022-1614-0083695

US3142056
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:49:47
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	06 Jan 2021 20:56:53

US3142056
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:49:47
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User closed query 'Per GCL Lab Reconciliation: Swab: Re query: Sample dated 21DEC2020 is recorded under Illness visit in PPD Central lab, however the same collection date is recorded in Covid-19 Assessment and COVID Diagnostic form details not updated in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 12:19:54
Query 'Per GCL Lab Reconciliation: Swab: Re query: Sample dated 21DEC2020 is recorded under Illness visit in PPD Central lab, however the same collection date is recorded in Covid-19 Assessment and COVID Diagnostic form details not updated in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' answered with 'see illness visit 21DEC2020 in EDC' (Site from DM).	Jill York (b) (4)	19 Apr 2021 17:18:41
User opened query 'Per GCL Lab Reconciliation: Swab: Re query: Sample dated 21DEC2020 is recorded under Illness visit in PPD Central lab, however the same collection date is recorded in Covid-19 Assessment and COVID Diagnostic form details not updated in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 12:20:04
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample Collection date is recorded as 21DEC2020 under Illness Visit Day 1 in PPD central lab. however same is missing in in EDC. Please update the details under appropriate visit Else clarify, thank you.' (Site from DM).		16 Apr 2021 12:20:04
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample Collection date is recorded as 21DEC2020 under Illness Visit Day 1 in PPD central lab. however same is missing in in EDC. Please update the details under appropriate visit Else clarify, thank you.' answered with 'site to enter' (Site from DM).	Jill York (b) (4)	07 Apr 2021 21:46:18

FDA-CBER-2022-1614-0083697

US3142056
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 23:26:17
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'information is correct ' (Site from System).	Meghan York (b) (4) (b) (4)	21 Jan 2021 16:59:51
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample Collection date is recorded as 21DEC2020 under Illness Visit Day 1 in PPD central lab. however same is missing in in EDC. Please update the details under appropriate visit Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 14:07:03
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	06 Jan 2021 20:56:53
User entered '6 Jan 2021'	Jami Wagner (b) (4) (b) (4)	06 Jan 2021 20:56:53

US3142056
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:49:47
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4) (b) (4)	06 Jan 2021 20:56:53

US3142056
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:49:47
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jami Wagner (b) (4) (b) (4)	06 Jan 2021 20:56:53

FDA-CBER-2022-1614-0083700

US3142056
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:49:47
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	06 Jan 2021 20:56:59

FDA-CBER-2022-1614-0083701

US3142056
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:49:47
User entered '1'	System	06 Jan 2021 20:56:59

FDA-CBER-2022-1614-0083702

US3142056
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:49:47
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	01 Feb 2021 22:18:28

FDA-CBER-2022-1614-0083703

US3142056
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:49:47
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, however corresponding illness visit details not updated in EDC. Please reconcile the data and update. Thank you.' (Site from DM).		26 Apr 2021 13:22:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, however corresponding illness visit details not updated in EDC. Please reconcile the data and update. Thank you.' answered with '11NOV2020 illness visit added' (Site from DM).	Jill York (b) (4)	23 Apr 2021 19:18:24
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, however corresponding illness visit details not updated in EDC. Please reconcile the data and update. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 12:14:41
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 11NOV2020 under Illness Visit Day 1 in PPD central lab, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' (Site from DM).		21 Apr 2021 12:14:41
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 11NOV2020 under Illness Visit Day 1 in PPD central lab, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' answered with 'Information has been entered for swab collection' (Site from DM).	Jami Wagner (b) (4) (b) (4)	19 Apr 2021 20:35:05
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 11NOV2020 under Illness Visit Day 1 in PPD central lab, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 06:22:34
User entered '26 Jan 2021'	Jami Wagner (b) (4) (b) (4)	01 Feb 2021 22:18:28

FDA-CBER-2022-1614-0083704

US3142056
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:49:47
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4) (b) (4)	01 Feb 2021 22:18:28

FDA-CBER-2022-1614-0083705

US3142056
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:49:47
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jami Wagner (b) (4) (b) (4)	01 Feb 2021 22:18:28

FDA-CBER-2022-1614-0083706

US3142056
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:49:47
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	01 Feb 2021 22:18:16

US3142056
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:49:47
User entered '1'	System	01 Feb 2021 22:18:16

FDA-CBER-2022-1614-0083708

US3142056
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:03:35

FDA-CBER-2022-1614-0083709

US3142056
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	02 Apr 2021 07:28:48
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'data is as documented' (Site from System).	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:03:58
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	01 Apr 2021 15:03:35
User entered '01 Apr 2021'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:03:35

US3142056
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Clinic (Clinic)'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:03:35

US3142056
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Folder OID

Audit	User	Time (GMT)
User entered 'VISIT4'	System	01 Apr 2021 15:03:35

US3142056
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:04:16

FDA-CBER-2022-1614-0083713

US3142056
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:04:16

FDA-CBER-2022-1614-0083714

US3142056
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:04:16

US3142056
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 15:04:16

US3142056
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:04:16

FDA-CBER-2022-1614-0083717

US3142056
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:04:16

US3142056
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:04:16

US3142056
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:04:16

US3142056
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Pulse units

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 15:04:16

FDA-CBER-2022-1614-0083721

US3142056
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:04:16

FDA-CBER-2022-1614-0083722

US3142056
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate units

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 15:04:16

US3142056
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:04:16

FDA-CBER-2022-1614-0083724

US3142056
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 15:04:16

US3142056
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:04:16

FDA-CBER-2022-1614-0083726

US3142056
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 15:04:16

US3142056
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:05:04

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US3142056
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:05:04

US3142056
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:00:27
Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:05:39

US3142056
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:00:27
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '01 Apr 2021'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:05:39

US3142056
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:00:27
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '08:20'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:05:39

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US3142056
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:00:27
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '01 Apr 2021 08:20'	System	01 Apr 2021 15:05:39

US3142056
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:05:47

US3142056
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 15:05:47

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:00:27
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:59
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Per review of Preclarus report, there is an Illness Swab Dated 21-Dec-2020 with Accession No: 1F654571629. However, this Swab data is missing in EDC. Kindly review Preclarus report and please update EDC as appropriate by initiating a Covid-19 Assessment page. Else, clarify. Thank you.' (Site from DM).		28 Apr 2021 14:24:41
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Per review of Preclarus report, there is an Illness Swab Dated 21-Dec-2020 with Accession No: 1F654571629. However, this Swab data is missing in EDC. Kindly review Preclarus report and please update EDC as appropriate by initiating a Covid-19 Assessment page. Else, clarify. Thank you.' answered with 'added to EDC' (Site from DM).	(b) (4) Jill York (b) (4)	23 Apr 2021 19:13:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:11:28
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Per review of Preclarus report, there is an Illness Swab Dated 21-Dec-2020 with Accession No: 1F654571629. However, this Swab data is missing in EDC. Kindly review Preclarus report and please update EDC as appropriate by initiating a Covid-19 Assessment page. Else, clarify. Thank you.' (Site from DM).		16 Apr 2021 05:16:25
User entered '11 Nov 2020'	Jill York (b) (4)	09 Apr 2021 21:41:56

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:00:27
Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:59
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:11:28
User entered '09:00'	Jill York (b) (4)	09 Apr 2021 21:41:56

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:00:27
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:59
User entered '11 Nov 2020 09:00'	System	09 Apr 2021 21:41:56

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:00:27
Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:59
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:11:28
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Jill York (b) (4)	09 Apr 2021 21:41:56

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:00:27
Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:59
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:11:28
User entered 'Yes (Y)'	Jill York (b) (4)	09 Apr 2021 21:41:56

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'Day 1 (Day 1)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:31:38

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered '09 Nov 2020' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered '17 Dec 2020'	Jill York (b) (4)	23 Apr 2021 18:31:38

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:42
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered '1'	Jill York (b) (4)	23 Apr 2021 18:31:38

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:48
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 18:31:38

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User entered empty.	System	23 Apr 2021 18:31:38

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:53
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 18:31:38

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	Jill York (b) (4)	23 Apr 2021 18:31:38

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Moderate (Moderate)'	Jill York (b) (4)	23 Apr 2021 18:31:38

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:31:38

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:59
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	Jill York (b) (4)	23 Apr 2021 18:31:38

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Moderate (Moderate)'	Jill York (b) (4)	23 Apr 2021 18:31:38

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:56:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:31:38

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:56:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:31:38

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:31:38

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:56:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	Jill York (b) (4)	23 Apr 2021 18:31:38

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:56:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	Jill York (b) (4)	23 Apr 2021 18:31:38

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:56:44
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:31:38

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:56:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:31:38

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:56:11
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	Jill York (b) (4)	23 Apr 2021 18:31:38

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	Jill York (b) (4)	23 Apr 2021 18:31:38

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:56:05
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	Jill York (b) (4)	23 Apr 2021 18:31:38

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:13
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:56:28
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	Jill York (b) (4)	23 Apr 2021 18:31:38

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'Day 2 (Day 2)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:33:05

FDA-CBER-2022-1614-0083763

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered '10 Nov 2020' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered '18 Dec 2020'	Jill York (b) (4)	23 Apr 2021 18:33:05

FDA-CBER-2022-1614-0083764

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered '1'	Jill York (b) (4)	23 Apr 2021 18:33:05

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 18:33:05

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User entered empty.	System	23 Apr 2021 18:33:05

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 18:33:05

FDA-CBER-2022-1614-0083768

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	Jill York (b) (4)	23 Apr 2021 18:33:05

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Moderate (Moderate)'	Jill York (b) (4)	23 Apr 2021 18:33:05

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:33:05

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:33:05

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Moderate (Moderate)'	Jill York (b) (4)	23 Apr 2021 18:33:05

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:33:05

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:33:05

FDA-CBER-2022-1614-0083775

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:33:05

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:33:05

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:33:05

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:33:05

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:33:05

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:33:05

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	Jill York (b) (4)	23 Apr 2021 18:33:05

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:33:05

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:17
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:33:05

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'Day 3 (Day 3)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:45:27

FDA-CBER-2022-1614-0083785

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered '11 Nov 2020' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered '19 Dec 2020'	Jill York (b) (4)	23 Apr 2021 18:45:27

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered '1'	Jill York (b) (4)	23 Apr 2021 18:45:27

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered '92' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 18:45:27

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User entered '%'	System	26 Apr 2021 20:55:24
User entered empty.	System	23 Apr 2021 18:45:27

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered '98.5' F reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 18:45:27

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	Jill York (b) (4)	23 Apr 2021 18:45:27

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Moderate (Moderate)'	Jill York (b) (4)	23 Apr 2021 18:45:27

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:45:27

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:45:27

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Moderate (Moderate)'	Jill York (b) (4)	23 Apr 2021 18:45:27

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:45:27

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:45:27

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:45:27

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:45:27

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:45:27

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:45:27

FDA-CBER-2022-1614-0083801

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:45:27

FDA-CBER-2022-1614-0083802

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:45:27

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	Jill York (b) (4) (b) (4)	23 Apr 2021 18:45:27

FDA-CBER-2022-1614-0083804

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:45:27

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:21
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:45:27

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'Day 4 (Day 4)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:46:42

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered '12 Nov 2020' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered '20 Dec 2020'	Jill York (b) (4)	23 Apr 2021 18:46:42

FDA-CBER-2022-1614-0083808

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:57:12
User entered '0' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:57:12
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered '1'	Jill York (b) (4)	23 Apr 2021 18:46:42

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered '96' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 18:46:42

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User entered '%'	System	26 Apr 2021 20:55:24
User entered empty.	System	23 Apr 2021 18:46:42

FDA-CBER-2022-1614-0083811

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered '98.0' F reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 18:46:42

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:46:42

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Moderate (Moderate)'	Jill York (b) (4)	23 Apr 2021 18:46:42

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:46:42

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:46:42

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Moderate (Moderate)'	Jill York (b) (4)	23 Apr 2021 18:46:42

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:46:42

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:46:42

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:46:42

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	Jill York (b) (4)	23 Apr 2021 18:46:42

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:46:42

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:46:42

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:46:42

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US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	Jill York (b) (4)	23 Apr 2021 18:46:42

FDA-CBER-2022-1614-0083825

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:46:42

FDA-CBER-2022-1614-0083826

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:46:42

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:25
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:46:42

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'Day 5 (Day 5)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:48:28

FDA-CBER-2022-1614-0083829

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered '13 Nov 2020' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered '21 Dec 2020'	Jill York (b) (4)	23 Apr 2021 18:48:28

FDA-CBER-2022-1614-0083830

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered '0'	Jill York (b) (4)	23 Apr 2021 18:48:28

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered '95' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered '91'	Jill York (b) (4)	23 Apr 2021 18:48:28

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User entered '%'	System	23 Apr 2021 18:48:28

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered '97.2' F reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered '97.5' F	Jill York (b) (4)	23 Apr 2021 18:48:28

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	Jill York (b) (4)	23 Apr 2021 18:48:28

FDA-CBER-2022-1614-0083835

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:48:28

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:48:28

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:48:28

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:48:28

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:48:28

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:48:28

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:08
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 20:55:24
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 20:55:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Apr 2021 18:48:28

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:48:28

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:48:28

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:48:28

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:48:28

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:48:28

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	Jill York (b) (4)	23 Apr 2021 18:48:28

FDA-CBER-2022-1614-0083848

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:48:28

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:28
Data hard unlocked.		03 May 2021 21:02:38
Data hard locked.		30 Apr 2021 14:01:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'None (None)'	(b) (4) Jill York (b) (4)	23 Apr 2021 18:48:28

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:00:27
Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:15
DataPoint Verified.		22 Apr 2021 17:11:51
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '11 Nov 2020'	Jill York (b) (4)	09 Apr 2021 21:42:28

FDA-CBER-2022-1614-0083851

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:00:27
Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:15
DataPoint Verified.		22 Apr 2021 17:11:51
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jill York (b) (4)	09 Apr 2021 21:42:28

FDA-CBER-2022-1614-0083852

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:00:27
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:15
DataPoint Verified.		22 Apr 2021 17:11:51
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	Jill York (b) (4)	09 Apr 2021 21:42:28

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:00:27
Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:15
DataPoint Verified.		22 Apr 2021 17:11:51
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '11 Nov 2020'	Jill York (b) (4)	09 Apr 2021 21:42:28

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:00:27
Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:15
DataPoint Verified.		22 Apr 2021 17:11:51
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jill York (b) (4) (b) (4)	09 Apr 2021 21:42:28

FDA-CBER-2022-1614-0083855

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:00:27
Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:15
DataPoint Verified.		22 Apr 2021 17:11:51
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Jill York (b) (4)	09 Apr 2021 21:42:28

FDA-CBER-2022-1614-0083856

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:00:27
Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:15
DataPoint Verified.		22 Apr 2021 17:11:51
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	Jill York (b) (4)	09 Apr 2021 21:42:28

FDA-CBER-2022-1614-0083857

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:00:27
Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:15
DataPoint Verified.		22 Apr 2021 17:11:51
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Jill York (b) (4)	09 Apr 2021 21:42:28

FDA-CBER-2022-1614-0083858

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:00:27
CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:15
DataPoint Verified.		22 Apr 2021 17:11:51
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Jill York (b) (4)	09 Apr 2021 21:42:28

FDA-CBER-2022-1614-0083859

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:00:27
COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:15
User entered '0'	System	09 Apr 2021 21:42:28

FDA-CBER-2022-1614-0083860

US3142056
Folder: Covid-19 Assessment 11 Nov 2020
Form: Generate Next COVID-19 Assessment
Generated On: 11 Aug 2021 22:00:27
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:27
DataPoint Verified.		22 Apr 2021 17:12:00
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Jill York (b) (4)	09 Apr 2021 21:44:29

FDA-CBER-2022-1614-0083861

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:00:27
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:16:08
User entered '21 Dec 2020'	Jill York (b) (4)	20 Apr 2021 15:16:04

FDA-CBER-2022-1614-0083862

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:00:27
Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:16:08
User entered '09:00'	Jill York (b) (4)	20 Apr 2021 15:16:04

FDA-CBER-2022-1614-0083863

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:00:27
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:35
User entered '21 Dec 2020 09:00'	System	20 Apr 2021 15:16:04

FDA-CBER-2022-1614-0083864

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:00:27
Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:16:08
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Jill York (b) (4)	20 Apr 2021 15:16:04

FDA-CBER-2022-1614-0083865

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:00:27
Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:35
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:16:08
User entered 'Yes (Y)'	Jill York (b) (4)	20 Apr 2021 15:16:04

FDA-CBER-2022-1614-0083866

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Day 1 (Day 1)'	Jill York (b) (4)	26 Apr 2021 18:46:35

FDA-CBER-2022-1614-0083867

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '17 Dec 2020'	Jill York (b) (4)	26 Apr 2021 18:46:35

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '1'	Jill York (b) (4)	26 Apr 2021 18:46:35

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 18:46:35

FDA-CBER-2022-1614-0083870

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
Data hard locked.		30 Apr 2021 14:01:43
User entered empty.	System	26 Apr 2021 18:46:35

FDA-CBER-2022-1614-0083871

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 18:46:35

FDA-CBER-2022-1614-0083872

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:46:35

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Moderate (Moderate)'	Jill York (b) (4)	26 Apr 2021 18:46:35

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:46:35

FDA-CBER-2022-1614-0083875

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:46:35

FDA-CBER-2022-1614-0083876

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Moderate (Moderate)'	Jill York (b) (4)	26 Apr 2021 18:46:35

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:46:35

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:46:35

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:46:35

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:46:35

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:46:35

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:46:35

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:46:35

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:46:35

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:46:35

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:46:35

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:46:35

FDA-CBER-2022-1614-0083888

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Day 2 (Day 2)'	Jill York (b) (4)	26 Apr 2021 18:47:56

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '18 Dec 2020'	Jill York (b) (4)	26 Apr 2021 18:47:56

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '1'	Jill York (b) (4)	26 Apr 2021 18:47:56

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 18:47:56

FDA-CBER-2022-1614-0083892

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
Data hard locked.		30 Apr 2021 14:01:43
User entered empty.	System	26 Apr 2021 18:47:56

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 18:47:56

FDA-CBER-2022-1614-0083894

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:47:56

FDA-CBER-2022-1614-0083895

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Moderate (Moderate)'	Jill York (b) (4)	26 Apr 2021 18:47:56

FDA-CBER-2022-1614-0083896

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:47:56

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:47:56

FDA-CBER-2022-1614-0083898

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Moderate (Moderate)'	Jill York (b) (4)	26 Apr 2021 18:47:56

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:47:56

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:47:56

FDA-CBER-2022-1614-0083901

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:47:56

FDA-CBER-2022-1614-0083902

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:47:56

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:47:56

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:47:56

FDA-CBER-2022-1614-0083905

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:47:56

FDA-CBER-2022-1614-0083906

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:47:56

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:47:56

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:47:56

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:47:56

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Day 3 (Day 3)'	Jill York (b) (4)	26 Apr 2021 18:49:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '19 Dec 2020'	Jill York (b) (4)	26 Apr 2021 18:49:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '1'	Jill York (b) (4)	26 Apr 2021 18:49:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 18:49:05

FDA-CBER-2022-1614-0083914

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
Data hard locked.		30 Apr 2021 14:01:43
User entered empty.	System	26 Apr 2021 18:49:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 18:49:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:49:05

FDA-CBER-2022-1614-0083917

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Moderate (Moderate)'	Jill York (b) (4)	26 Apr 2021 18:49:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:49:05

FDA-CBER-2022-1614-0083919

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:49:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Moderate (Moderate)'	Jill York (b) (4)	26 Apr 2021 18:49:05

FDA-CBER-2022-1614-0083921

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:49:05

FDA-CBER-2022-1614-0083922

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:49:05

FDA-CBER-2022-1614-0083923

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:49:05

FDA-CBER-2022-1614-0083924

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:49:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:49:05

FDA-CBER-2022-1614-0083926

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:49:05

FDA-CBER-2022-1614-0083927

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:49:05

FDA-CBER-2022-1614-0083928

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:49:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:49:05

FDA-CBER-2022-1614-0083930

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:49:05

FDA-CBER-2022-1614-0083931

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:49:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Day 4 (Day 4)'	Jill York (b) (4)	26 Apr 2021 18:50:15

FDA-CBER-2022-1614-0083933

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '20 Dec 2020'	Jill York (b) (4)	26 Apr 2021 18:50:15

FDA-CBER-2022-1614-0083934

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '1'	Jill York (b) (4)	26 Apr 2021 18:50:15

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 18:50:15

FDA-CBER-2022-1614-0083936

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
Data hard locked.		30 Apr 2021 14:01:43
User entered empty.	System	26 Apr 2021 18:50:15

FDA-CBER-2022-1614-0083937

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 18:50:15

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:50:15

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Moderate (Moderate)'	Jill York (b) (4)	26 Apr 2021 18:50:15

FDA-CBER-2022-1614-0083940

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:50:15

FDA-CBER-2022-1614-0083941

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:50:15

FDA-CBER-2022-1614-0083942

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Moderate (Moderate)'	Jill York (b) (4)	26 Apr 2021 18:50:15

FDA-CBER-2022-1614-0083943

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:50:15

FDA-CBER-2022-1614-0083944

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:50:15

FDA-CBER-2022-1614-0083945

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:50:15

FDA-CBER-2022-1614-0083946

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:50:15

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:50:15

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:50:15

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:50:15

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:50:15

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:50:15

FDA-CBER-2022-1614-0083952

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:50:15

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:50:15

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Day 5 (Day 5)'	Jill York (b) (4)	26 Apr 2021 18:51:34

FDA-CBER-2022-1614-0083955

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '21 Dec 2020'	Jill York (b) (4)	26 Apr 2021 18:51:34

FDA-CBER-2022-1614-0083956

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '0'	Jill York (b) (4)	26 Apr 2021 18:51:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '91'	Jill York (b) (4)	26 Apr 2021 18:51:34

FDA-CBER-2022-1614-0083958

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
Data hard locked.		30 Apr 2021 14:01:43
User entered '%'	System	26 Apr 2021 18:51:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '97.5' F	Jill York (b) (4)	26 Apr 2021 18:51:34

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US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:51:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:51:34

FDA-CBER-2022-1614-0083962

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:51:34

FDA-CBER-2022-1614-0083963

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:51:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:51:34

FDA-CBER-2022-1614-0083965

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:51:34

FDA-CBER-2022-1614-0083966

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:51:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:51:34

FDA-CBER-2022-1614-0083968

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:51:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:51:34

FDA-CBER-2022-1614-0083970

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:51:34

FDA-CBER-2022-1614-0083971

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:51:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:51:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:51:34

FDA-CBER-2022-1614-0083974

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:51:34

FDA-CBER-2022-1614-0083975

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:51:34

FDA-CBER-2022-1614-0083976

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Day 6 (Day 6)'	Jill York (b) (4)	26 Apr 2021 18:52:39

FDA-CBER-2022-1614-0083977

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '22 Dec 2020'	Jill York (b) (4)	26 Apr 2021 18:52:39

FDA-CBER-2022-1614-0083978

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '0'	Jill York (b) (4)	26 Apr 2021 18:52:39

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '94'	Jill York (b) (4)	26 Apr 2021 18:52:39

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
Data hard locked.		30 Apr 2021 14:01:43
User entered '%'	System	26 Apr 2021 18:52:39

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '97.0' F	Jill York (b) (4)	26 Apr 2021 18:52:39

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:52:39

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:52:39

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:52:39

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:52:39

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:52:39

FDA-CBER-2022-1614-0083987

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:52:39

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:52:39

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:52:39

FDA-CBER-2022-1614-0083990

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:52:39

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:52:39

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:52:39

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:52:39

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:52:39

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:52:39

FDA-CBER-2022-1614-0083996

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:52:39

FDA-CBER-2022-1614-0083997

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:52:39

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Day 7 (Day 7)'	Jill York (b) (4)	26 Apr 2021 18:54:00

FDA-CBER-2022-1614-0083999

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '23 Dec 2020'	Jill York (b) (4)	26 Apr 2021 18:54:00

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '0'	Jill York (b) (4)	26 Apr 2021 18:54:00

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '94'	Jill York (b) (4)	26 Apr 2021 18:54:00

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
Data hard locked.		30 Apr 2021 14:01:43
User entered '%'	System	26 Apr 2021 18:54:00

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '97.1' F	Jill York (b) (4)	26 Apr 2021 18:54:00

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:54:00

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:54:00

FDA-CBER-2022-1614-0084006

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:54:00

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:54:00

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:54:00

FDA-CBER-2022-1614-0084009

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:54:00

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:54:00

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:54:00

FDA-CBER-2022-1614-0084012

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:54:00

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:54:00

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:54:00

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:54:00

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:54:00

FDA-CBER-2022-1614-0084017

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:54:00

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:54:00

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:54:00

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Day 8 (Day 8)'	Jill York (b) (4)	26 Apr 2021 18:55:09

FDA-CBER-2022-1614-0084021

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '24 Dec 2020'	Jill York (b) (4)	26 Apr 2021 18:55:09

FDA-CBER-2022-1614-0084022

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '0'	Jill York (b) (4)	26 Apr 2021 18:55:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '94'	Jill York (b) (4)	26 Apr 2021 18:55:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
Data hard locked.		30 Apr 2021 14:01:43
User entered '%'	System	26 Apr 2021 18:55:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '97.4' F	Jill York (b) (4)	26 Apr 2021 18:55:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:55:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:55:09

FDA-CBER-2022-1614-0084028

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:55:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:55:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:55:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:55:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:55:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:55:09

FDA-CBER-2022-1614-0084034

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:55:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:55:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:55:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:55:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:55:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:55:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:55:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:55:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Day 9 (Day 9)'	Jill York (b) (4)	26 Apr 2021 18:56:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '25 Dec 2020'	Jill York (b) (4)	26 Apr 2021 18:56:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '1'	Jill York (b) (4)	26 Apr 2021 18:56:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 18:56:09

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US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
Data hard locked.		30 Apr 2021 14:01:43
User entered empty.	System	26 Apr 2021 18:56:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 18:56:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:56:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:56:09

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US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:56:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:56:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:56:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:56:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:56:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:56:09

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US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:56:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:56:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:56:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:56:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:56:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:56:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:56:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:56:09

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Day 10 (Day 10)'	Jill York (b) (4)	26 Apr 2021 18:59:22

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '26 Dec 2020'	Jill York (b) (4)	26 Apr 2021 18:59:22

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '0'	Jill York (b) (4)	26 Apr 2021 18:59:22

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '94'	Jill York (b) (4)	26 Apr 2021 18:59:22

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
Data hard locked.		30 Apr 2021 14:01:43
User entered '%'	System	26 Apr 2021 18:59:22

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '97.1' F	Jill York (b) (4)	26 Apr 2021 18:59:22

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US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:59:22

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:59:22

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US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:59:22

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:59:22

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:59:22

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US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:59:22

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:59:22

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 18:59:22

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:59:22

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:59:22

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:59:22

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:59:22

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:59:22

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:59:22

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:59:22

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 18:59:22

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Day 11 (Day 11)'	Jill York (b) (4)	26 Apr 2021 19:00:57

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Apr 2021 19:01:08
User entered '27 Dec 2020' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:01:08
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Apr 2021 19:00:57
User entered '37 Dec 2020' (non-conformant).	Jill York (b) (4)	26 Apr 2021 19:00:57

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '0'	Jill York (b) (4)	26 Apr 2021 19:00:57

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '95'	Jill York (b) (4)	26 Apr 2021 19:00:57

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
Data hard locked.		30 Apr 2021 14:01:43
User entered '%'	System	26 Apr 2021 19:00:57

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '97.4' F	Jill York (b) (4)	26 Apr 2021 19:00:57

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:00:57

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 19:00:57

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:00:57

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:00:57

FDA-CBER-2022-1614-0084096

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 19:00:57

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:00:57

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:00:57

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 19:00:57

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US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:00:57

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:00:57

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:00:57

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:00:57

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:00:57

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:00:57

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:00:57

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:00:57

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:03:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 19:01:08

FDA-CBER-2022-1614-0084109

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 19:03:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Apr 2021 19:03:43
User entered '28 Dec 2020' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:03:43
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 19:01:08
User entered empty.	Jill York (b) (4)	26 Apr 2021 19:01:08

FDA-CBER-2022-1614-0084110

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '0'	Jill York (b) (4)	26 Apr 2021 19:01:08

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '95' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:03:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 19:01:08

FDA-CBER-2022-1614-0084112

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
Data hard locked.		30 Apr 2021 14:01:43
User entered '%'	System	26 Apr 2021 19:03:43
User entered empty.	System	26 Apr 2021 19:01:08

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '96.6' F reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:03:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 19:01:08

FDA-CBER-2022-1614-0084114

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:03:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 19:01:08

FDA-CBER-2022-1614-0084115

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:03:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 19:01:08

FDA-CBER-2022-1614-0084116

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:03:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 19:01:08

FDA-CBER-2022-1614-0084117

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:03:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 19:01:08

FDA-CBER-2022-1614-0084118

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:03:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 19:01:08

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:03:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 19:01:08

FDA-CBER-2022-1614-0084120

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:03:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 19:01:08

FDA-CBER-2022-1614-0084121

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:03:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 19:01:08

FDA-CBER-2022-1614-0084122

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:03:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 19:01:08

FDA-CBER-2022-1614-0084123

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:03:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 19:01:08

FDA-CBER-2022-1614-0084124

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:03:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 19:01:08

FDA-CBER-2022-1614-0084125

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:03:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 19:01:08

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:03:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 19:01:08

FDA-CBER-2022-1614-0084127

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:03:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 19:01:08

FDA-CBER-2022-1614-0084128

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:03:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 19:01:08

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:03:43
User entered empty.	Jill York (b) (4)	26 Apr 2021 19:01:08

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Day 13 (Day 13)'	Jill York (b) (4)	26 Apr 2021 19:05:05

FDA-CBER-2022-1614-0084131

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '29 Dec 2020'	Jill York (b) (4)	26 Apr 2021 19:05:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '0'	Jill York (b) (4)	26 Apr 2021 19:05:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '95'	Jill York (b) (4)	26 Apr 2021 19:05:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
Data hard locked.		30 Apr 2021 14:01:43
User entered '%'	System	26 Apr 2021 19:05:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '96.4' F	Jill York (b) (4)	26 Apr 2021 19:05:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:05:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 19:05:05

FDA-CBER-2022-1614-0084138

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:05:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:05:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:05:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:05:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:05:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:05:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:05:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:05:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:05:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:05:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:05:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:05:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:05:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:05:05

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Day 14 (Day 14)'	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '30 Dec 2020'	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '0'	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '94'	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
Data hard locked.		30 Apr 2021 14:01:43
User entered '%'	System	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '96.5' F	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:06:32

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Day 15 (Day 15)'	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '31 Dec 2020'	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '0'	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '96'	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
Data hard locked.		30 Apr 2021 14:01:43
User entered '%'	System	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '96.9' F	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:07:50

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Day 16 (Day 16)'	Jill York (b) (4)	26 Apr 2021 19:09:24

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '01 Jan 2021'	Jill York (b) (4)	26 Apr 2021 19:09:24

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US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '0'	Jill York (b) (4)	26 Apr 2021 19:09:24

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '97'	Jill York (b) (4)	26 Apr 2021 19:09:24

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
Data hard locked.		30 Apr 2021 14:01:43
User entered '%'	System	26 Apr 2021 19:09:24

FDA-CBER-2022-1614-0084201

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '97.0' F	Jill York (b) (4)	26 Apr 2021 19:09:24

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:09:24

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 19:09:24

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:09:24

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:09:24

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:09:24

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:09:24

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:09:24

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:09:24

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:09:24

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:09:24

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:09:24

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:09:24

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:09:24

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:09:24

FDA-CBER-2022-1614-0084216

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:09:24

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:09:24

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Day 17 (Day 17)'	Jill York (b) (4)	26 Apr 2021 19:10:34

FDA-CBER-2022-1614-0084219

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '02 Jan 2021'	Jill York (b) (4)	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '0'	Jill York (b) (4)	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '96'	Jill York (b) (4)	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
Data hard locked.		30 Apr 2021 14:01:43
User entered '%'	System	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '96.1' F	Jill York (b) (4)	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Mild (Mild)'	Jill York (b) (4)	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:10:34

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Day 18 (Day 18)'	Jill York (b) (4)	26 Apr 2021 19:11:30

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US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '03 Jan 2021'	Jill York (b) (4)	26 Apr 2021 19:11:30

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '0'	Jill York (b) (4)	26 Apr 2021 19:11:30

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '96'	Jill York (b) (4)	26 Apr 2021 19:11:30

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
Data hard locked.		30 Apr 2021 14:01:43
User entered '%'	System	26 Apr 2021 19:11:30

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '97.2' F	Jill York (b) (4)	26 Apr 2021 19:11:30

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:11:30

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:11:30

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:11:30

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:11:30

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:11:30

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:11:30

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US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:11:30

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:11:30

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:11:30

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:11:30

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:11:30

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US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:11:30

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:11:30

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:11:30

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:11:30

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:11:30

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'Day 22 (Day 22)'	Jill York (b) (4)	26 Apr 2021 19:12:31

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '10 Jan 2021'	Jill York (b) (4)	26 Apr 2021 19:12:31

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US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '0'	Jill York (b) (4)	26 Apr 2021 19:12:31

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '97'	Jill York (b) (4)	26 Apr 2021 19:12:31

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
Data hard locked.		30 Apr 2021 14:01:43
User entered '%'	System	26 Apr 2021 19:12:31

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered '96.3' F	Jill York (b) (4)	26 Apr 2021 19:12:31

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:12:31

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:12:31

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:12:31

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:12:31

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:12:31

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:12:31

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:12:31

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:12:31

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:12:31

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:12:31

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US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:12:31

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:12:31

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:12:31

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:12:31

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:12:31

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:00:27
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:02
Data hard unlocked.		03 May 2021 21:03:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:43
User entered 'None (None)'	Jill York (b) (4)	26 Apr 2021 19:12:31

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:00:27
Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:51
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:16:20
User entered '21 Dec 2020'	Jill York (b) (4)	20 Apr 2021 15:16:48

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US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:00:27
Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:51
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:16:20
User entered 'Yes (Y)'	Jill York (b) (4)	20 Apr 2021 15:16:48

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:00:27
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:16:20
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).		21 Apr 2021 09:45:22
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'it is already entered on AE folder in edc' (Site from System).	Jill York (b) (4)	20 Apr 2021 15:17:36
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	20 Apr 2021 15:16:48
User entered 'Yes (Y)'	Jill York (b) (4)	20 Apr 2021 15:16:48

FDA-CBER-2022-1614-0084287

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:00:27
Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:51
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:16:20
User entered '21 Dec 2020'	Jill York (b) (4)	20 Apr 2021 15:16:48

FDA-CBER-2022-1614-0084288

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:00:27
Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:16:20
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jill York (b) (4)	20 Apr 2021 15:16:48

FDA-CBER-2022-1614-0084289

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:00:27
Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:51
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:16:20
User entered empty.	Jill York (b) (4)	20 Apr 2021 15:16:48

FDA-CBER-2022-1614-0084290

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:00:27
Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:51
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:16:20
User entered 'No (N)'	Jill York (b) (4)	20 Apr 2021 15:16:48

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:00:27
Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:51
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:16:20
User entered empty.	Jill York (b) (4)	20 Apr 2021 15:16:48

FDA-CBER-2022-1614-0084292

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:00:27
CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:51
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:16:20
User entered empty.	Jill York (b) (4)	20 Apr 2021 15:16:48

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:00:27
COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:51
User entered '1'	System	20 Apr 2021 15:16:48

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US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'No (N)'	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Did the subject have Heart Rate ≥ 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'No (N)'	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Heart Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
User signature succeeded.	Ripley Hollister (b) (4)	03 May 2021 15:03:34
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 19:17:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:17:03
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'No (N)'	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
User signature succeeded.	Ripley Hollister (b) (4)	03 May 2021 15:03:34
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 19:17:03
User entered '21 Dec 2020' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:17:03
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 19:17:03
User entered '21 Dec 2020' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:17:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 19:17:03
User entered '91' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 19:17:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'No (N)'	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
PaO2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'No (N)'	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 16:17:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 16:17:21
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	23 Apr 2021 16:17:21
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 16:17:03
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
High-Flow Oxygen?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'No (N)'	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Non-Invasive Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'No (N)'	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Mechanical Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'No (N)'	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

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US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
ECMO?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'No (N)'	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

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Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'No (N)'	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Evidence of Shock Requires Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'No (N)'	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Acute Renal Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'No (N)'	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Hepatic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'No (N)'	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Neurologic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'No (N)'	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Clinical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'No (N)'	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Radiographical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'No (N)'	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Admission to an intensive care unit due to SARS-CoV-2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 16:17:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 16:17:21
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	23 Apr 2021 16:17:21
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 16:17:03
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Covid-19 Assessment 21 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:00:27
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:16
DataPoint Verified.		30 Apr 2021 21:23:10
Data hard unlocked.	KC Joubran (b) (4) (b) (4)	30 Apr 2021 20:26:13
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:01:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 16:17:03

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:00:27
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

FDA-CBER-2022-1614-0084346

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:00:27
Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:41
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:00:27
Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:41
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:00:27
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

FDA-CBER-2022-1614-0084349

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:00:27
Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:41
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:00:27
Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:41
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 22:00:27
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

FDA-CBER-2022-1614-0084352

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 22:00:27
Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:41
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 22:00:27
Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:41
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

FDA-CBER-2022-1614-0084354

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:00:27
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

FDA-CBER-2022-1614-0084355

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:00:27
Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:41
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:00:27
Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:41
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:00:27
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

FDA-CBER-2022-1614-0084358

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:00:27
Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:41
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:00:27
Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:41
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:00:27
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

FDA-CBER-2022-1614-0084361

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:00:27
Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:41
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:00:27
Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:41
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:00:27
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:00:27
Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:41
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

US3142056
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:00:27
Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:41
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:56:14

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:00:27
Visit

Audit	User		Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jill York	(b) (4)	23 Apr 2021 19:17:41

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:00:27
Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'NA (COVID-19 Negative) (NA)'	Jill York (b) (4)	23 Apr 2021 19:17:41

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:00:27
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:17:41

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:00:27
Visit

Audit	User		Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jill York	(b) (4)	23 Apr 2021 19:17:41

FDA-CBER-2022-1614-0084370

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:00:27
Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'NA (COVID-19 Negative) (NA)'	Jill York (b) (4)	23 Apr 2021 19:17:41

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:00:27
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:17:41

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 22:00:27
Visit

Audit	User		Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jill York	(b) (4)	23 Apr 2021 19:17:41

FDA-CBER-2022-1614-0084373

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 22:00:27
Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'NA (COVID-19 Negative) (NA)'	Jill York (b) (4)	23 Apr 2021 19:17:41

FDA-CBER-2022-1614-0084374

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 22:00:27
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:17:41

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:00:27
Visit

Audit	User		Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jill York	(b) (4)	23 Apr 2021 19:17:41

FDA-CBER-2022-1614-0084376

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:00:27
Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'NA (COVID-19 Negative) (NA)'	Jill York (b) (4)	23 Apr 2021 19:17:41

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:00:27
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:17:41

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:00:27
Visit

Audit	User		Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jill York	(b) (4)	23 Apr 2021 19:17:41

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:00:27
Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'NA (COVID-19 Negative) (NA)'	Jill York (b) (4)	23 Apr 2021 19:17:41

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:00:27
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:17:41

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:00:27
Visit

Audit	User		Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jill York	(b) (4)	23 Apr 2021 19:17:41

FDA-CBER-2022-1614-0084382

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:00:27
Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'NA (COVID-19 Negative) (NA)'	Jill York (b) (4)	23 Apr 2021 19:17:41

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:00:27
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:17:41

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:00:27
Visit

Audit	User		Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jill York	(b) (4)	23 Apr 2021 19:17:41

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:00:27
Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'NA (COVID-19 Negative) (NA)'	Jill York (b) (4)	23 Apr 2021 19:17:41

US3142056
Folder: Illness Visit (2)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:00:27
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:17:41

US3142056
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
DataPoint Verified.		22 Apr 2021 17:12:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Per review of Preclarus report, there is an Illness Swab Dated 21-Dec-2020 with Accession No: 1F654571629. However, this Swab data is missing in EDC. Kindly review Preclarus report and please update EDC as appropriate by initiating a Covid-19 Assessment page. Else, clarify. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 05:16:13
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Per review of Preclarus report, there is an Illness Swab Dated 21-Dec-2020 with Accession No: 1F654571629. However, this Swab data is missing in EDC. Kindly review Preclarus report and please update EDC as appropriate by initiating a Covid-19 Assessment page. Else, clarify. Thank you.' (Site from DM).		16 Apr 2021 05:16:03
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	09 Apr 2021 17:33:14

FDA-CBER-2022-1614-0084388

US3142056
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
DataPoint Verified.		22 Apr 2021 17:12:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '21 Dec 2020'	Lisa Jackson (b) (4) (b) (4)	09 Apr 2021 17:33:14

US3142056
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
DataPoint Verified.		22 Apr 2021 17:12:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Clinic (Clinic)'	Lisa Jackson (b) (4) (b) (4)	09 Apr 2021 17:33:14

US3142056
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User entered 'SICKD1'	System	09 Apr 2021 17:33:14

FDA-CBER-2022-1614-0084391

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
DataPoint Verified.		22 Apr 2021 17:12:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	09 Apr 2021 17:35:01

FDA-CBER-2022-1614-0084392

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
DataPoint Verified.		22 Apr 2021 17:12:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '21 Dec 2020'	Lisa Jackson (b) (4) (b) (4)	09 Apr 2021 17:35:01

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
DataPoint Verified.		22 Apr 2021 17:12:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '09:10'	Lisa Jackson (b) (4) (b) (4)	09 Apr 2021 17:35:01

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User entered '21 Dec 2020 09:10'	System	09 Apr 2021 17:35:01

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
DataPoint Verified.		22 Apr 2021 17:12:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered missing code ND - Not Done.	Lisa Jackson (b) (4) (b) (4)	09 Apr 2021 17:35:01
DataPoint set to visible.	System	09 Apr 2021 17:33:14

FDA-CBER-2022-1614-0084396

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
DataPoint Verified.		22 Apr 2021 17:12:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered missing code ND - Not Done.	Lisa Jackson (b) (4) (b) (4)	09 Apr 2021 17:35:01
DataPoint set to visible.	System	09 Apr 2021 17:33:14

FDA-CBER-2022-1614-0084397

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
DataPoint Verified.		22 Apr 2021 17:12:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '97.5' F	Lisa Jackson (b) (4) (b) (4)	09 Apr 2021 17:35:01

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
DataPoint Verified.		22 Apr 2021 17:12:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Other (Other)'	Lisa Jackson (b) (4) (b) (4)	09 Apr 2021 17:35:01

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
DataPoint Verified.		22 Apr 2021 17:12:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'TEMPORAL'	Lisa Jackson (b) (4) (b) (4)	09 Apr 2021 17:35:01

FDA-CBER-2022-1614-0084400

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
DataPoint Verified.		22 Apr 2021 17:12:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '84'	Lisa Jackson (b) (4) (b) (4)	09 Apr 2021 17:35:01

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User entered 'bpm'	System	09 Apr 2021 17:35:01

FDA-CBER-2022-1614-0084402

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
DataPoint Verified.		22 Apr 2021 17:12:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '14'	Lisa Jackson (b) (4) (b) (4)	09 Apr 2021 17:35:01

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User entered 'breaths/min'	System	09 Apr 2021 17:35:01

FDA-CBER-2022-1614-0084404

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
DataPoint Verified.		22 Apr 2021 17:12:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '128'	Lisa Jackson (b) (4) (b) (4)	09 Apr 2021 17:35:01

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User entered 'mmHg'	System	09 Apr 2021 17:35:01

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
DataPoint Verified.		22 Apr 2021 17:12:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '76'	Lisa Jackson (b) (4) (b) (4)	09 Apr 2021 17:35:01

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User entered 'mmHg'	System	09 Apr 2021 17:35:01

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06

FDA-CBER-2022-1614-0084409

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06

FDA-CBER-2022-1614-0084410

US3142056
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
DataPoint Verified.		22 Apr 2021 17:12:40
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	09 Apr 2021 17:35:26

FDA-CBER-2022-1614-0084411

US3142056
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
DataPoint Verified.		22 Apr 2021 17:12:40
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '21 Dec 2020'	Lisa Jackson (b) (4) (b) (4)	09 Apr 2021 17:35:26

US3142056
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:00:27
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:06:13
Data hard unlocked.		03 May 2021 21:03:23
Data hard locked.		30 Apr 2021 19:16:06
DataPoint Verified.		22 Apr 2021 17:12:45
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	09 Apr 2021 17:36:27

US3142056
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:00:27
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:06:13
Data hard unlocked.		03 May 2021 21:03:23
Data hard locked.		30 Apr 2021 19:16:06
DataPoint Verified.		22 Apr 2021 17:12:45
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '21 Dec 2020'	Lisa Jackson (b) (4) (b) (4)	09 Apr 2021 17:36:27

US3142056
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Yes (Y)'	Jill York (b) (4)	23 Apr 2021 19:15:23

US3142056
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered '11 Nov 2020'	Jill York (b) (4)	23 Apr 2021 19:15:23

US3142056
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Clinic (Clinic)'	Jill York (b) (4)	23 Apr 2021 19:15:23

US3142056
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User entered 'SICKD1'	System	23 Apr 2021 19:15:23

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Yes (Y)'	Jill York (b) (4)	23 Apr 2021 19:16:29

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered '11 Nov 2020'	Jill York (b) (4)	23 Apr 2021 19:16:29

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US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered '09:12'	Jill York (b) (4)	23 Apr 2021 19:16:29

FDA-CBER-2022-1614-0084421

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User entered '11 Nov 2020 09:12'	System	23 Apr 2021 19:16:29

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered missing code ND - Not Done.	Jill York (b) (4)	23 Apr 2021 19:16:29
DataPoint set to visible.	System	23 Apr 2021 19:15:23

FDA-CBER-2022-1614-0084423

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered missing code ND - Not Done.	Jill York (b) (4)	23 Apr 2021 19:16:29
DataPoint set to visible.	System	23 Apr 2021 19:15:23

FDA-CBER-2022-1614-0084424

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered '98.5' F	Jill York (b) (4)	23 Apr 2021 19:16:29

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Other (Other)'	Jill York (b) (4)	23 Apr 2021 19:16:29

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'temporal'	Jill York (b) (4)	23 Apr 2021 19:16:29

FDA-CBER-2022-1614-0084427

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered '88'	Jill York (b) (4)	23 Apr 2021 19:16:29

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US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User entered 'bpm'	System	23 Apr 2021 19:16:29

FDA-CBER-2022-1614-0084429

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered '14'	Jill York (b) (4)	23 Apr 2021 19:16:29

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User entered 'breaths/min'	System	23 Apr 2021 19:16:29

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered '148'	Jill York (b) (4)	23 Apr 2021 19:16:29

FDA-CBER-2022-1614-0084432

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User entered 'mmHg'	System	23 Apr 2021 19:16:29

FDA-CBER-2022-1614-0084433

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered '78'	Jill York (b) (4)	23 Apr 2021 19:16:29

FDA-CBER-2022-1614-0084434

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User entered 'mmHg'	System	23 Apr 2021 19:16:29

FDA-CBER-2022-1614-0084435

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06

FDA-CBER-2022-1614-0084436

US3142056
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06

FDA-CBER-2022-1614-0084437

US3142056
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'Yes (Y)'	Jill York (b) (4)	23 Apr 2021 19:16:39

US3142056
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered '11 Nov 2020'	Jill York (b) (4)	23 Apr 2021 19:16:39

FDA-CBER-2022-1614-0084439

US3142056
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:00:27
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'NA (COVID-19 Negative) (NA)'	Jill York (b) (4)	23 Apr 2021 19:16:52

US3142056
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:00:27
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:34
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:06
User closed query 'Per GCL Lab Recon: SARS-COV2: Please kindly update the missing SARS sample collection date in this field.Thank you.' (Site from DM).		28 Apr 2021 16:35:51
Query 'Per GCL Lab Recon: SARS-COV2: Please kindly update the missing SARS sample collection date in this field.Thank you.' answered with 'done' (Site from DM).	Jill York (b) (4)	26 Apr 2021 21:01:22
Signature has been broken.	Jill York (b) (4)	26 Apr 2021 21:00:52
User entered '11 Nov 2020' reason for change: Data Entry Error	Jill York (b) (4)	26 Apr 2021 21:00:52
User opened query 'Per GCL Lab Recon: SARS-COV2: Please kindly update the missing SARS sample collection date in this field.Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 12:14:36
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:16:52

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
DataPoint Verified.		22 Apr 2021 17:13:00
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:47:28

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
DataPoint Verified.		22 Apr 2021 17:13:00
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '28 Jan 2021' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 19:50:39
User entered '21 Dec 2020'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:47:28

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
DataPoint Verified.		22 Apr 2021 17:13:00
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Clinic (Clinic)'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:47:28

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User entered 'SICKD28'	System	08 Apr 2021 22:47:28

FDA-CBER-2022-1614-0084445

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
DataPoint Verified.		22 Apr 2021 17:13:14
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:50:21

FDA-CBER-2022-1614-0084446

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
DataPoint Verified.		22 Apr 2021 17:13:14
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Apr 2021 19:52:04
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	15 Apr 2021 19:52:04
User entered '28 Jan 2021' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 19:52:04
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Apr 2021 19:50:39
User entered '21 Dec 2020'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:50:21

FDA-CBER-2022-1614-0084447

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
DataPoint Verified.		22 Apr 2021 17:13:14
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '08:00' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 19:52:04
User entered '09:10'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:50:21

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User entered '28 Jan 2021 08:00'	System	15 Apr 2021 19:52:04
User entered '21 Dec 2020 09:10'	System	08 Apr 2021 22:50:21

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
DataPoint Verified.		22 Apr 2021 17:13:14
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '97.0' F reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 19:52:04
User entered '97.5' F	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:50:21

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
DataPoint Verified.		22 Apr 2021 17:13:14
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Other (Other)'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:50:21

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
DataPoint Verified.		22 Apr 2021 17:13:14
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'TEMPORAL'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:50:21

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
DataPoint Verified.		22 Apr 2021 17:13:14
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '72' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 19:52:04
User entered '84'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:50:21

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User entered 'bpm'	System	08 Apr 2021 22:50:21

FDA-CBER-2022-1614-0084454

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
DataPoint Verified.		22 Apr 2021 17:13:14
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '16' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 19:52:04
User entered '14'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:50:21

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User entered 'breaths/min'	System	08 Apr 2021 22:50:21

FDA-CBER-2022-1614-0084456

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
DataPoint Verified.		22 Apr 2021 17:13:14
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '126' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 19:52:04
User entered '128'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:50:21

FDA-CBER-2022-1614-0084457

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User entered 'mmHg'	System	08 Apr 2021 22:50:21

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
Signature has been broken indirectly.	System	23 Apr 2021 19:17:02
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:13:14
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '98' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 19:52:04
User entered '76'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:50:21

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User entered 'mmHg'	System	08 Apr 2021 22:50:21

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20

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US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
DataPoint Verified.		22 Apr 2021 17:13:27
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:50:57

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
DataPoint Verified.		22 Apr 2021 17:13:27
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Apr 2021 19:52:34
User entered '28 Jan 2021' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 19:52:34
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Apr 2021 19:50:39
User entered '21 Dec 2020'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:50:57

FDA-CBER-2022-1614-0084464

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:00:27
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
DataPoint Verified.		22 Apr 2021 17:13:41
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:54:16

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:00:27
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
DataPoint Verified.		22 Apr 2021 17:13:41
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 21DEC2020 is reported under Convalescence Visit Day 28 in EDC, however the same SARS-CoV-2 serum sample is reported in the illness visit Day 1 in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).		20 Apr 2021 05:42:09
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 21DEC2020 is reported under Convalescence Visit Day 28 in EDC, however the same SARS-CoV-2 serum sample is reported in the illness visit Day 1 in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Data was incorrect before. Subject's data is updated now through Source and Lab Requisitions. Lab Req form number is 28JAN2021 ILLNESS VISIT D28 KIT TYPE E 1F605075542' (Site from DM).	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 19:57:56
User entered '28 Jan 2021' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 19:53:06
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 21DEC2020 is reported under Convalescence Visit Day 28 in EDC, however the same SARS-CoV-2 serum sample is reported in the illness visit Day 1 in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 07:32:55
User entered '21 Dec 2020'	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 22:54:16

FDA-CBER-2022-1614-0084466

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'No (N)'	Jill York (b) (4)	23 Apr 2021 19:17:02

FDA-CBER-2022-1614-0084467

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:17:02

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:17:02

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User entered 'SICKD28'	System	23 Apr 2021 19:17:02

FDA-CBER-2022-1614-0084470

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'No (N)'	Jill York (b) (4)	23 Apr 2021 19:17:11

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:17:11

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:17:11

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User entered empty.	System	23 Apr 2021 19:17:11

FDA-CBER-2022-1614-0084474

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:17:11

FDA-CBER-2022-1614-0084475

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:17:11

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:17:11

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:17:11

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User entered empty.	System	23 Apr 2021 19:17:11

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:17:11

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User entered empty.	System	23 Apr 2021 19:17:11

FDA-CBER-2022-1614-0084481

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:17:11

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User entered empty.	System	23 Apr 2021 19:17:11

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:17:11

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User entered empty.	System	23 Apr 2021 19:17:11

FDA-CBER-2022-1614-0084485

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20

FDA-CBER-2022-1614-0084486

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:00:27
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20

FDA-CBER-2022-1614-0084487

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered 'No (N)'	Jill York (b) (4)	23 Apr 2021 19:17:17

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:17:17

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:00:27
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:56
User entered 'NA (COVID-19 Negative) (NA)'	Jill York (b) (4)	23 Apr 2021 19:17:23

US3142056
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:00:27
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User entered empty.	Jill York (b) (4)	23 Apr 2021 19:17:23

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User closed query 'Please verify and enter the missing COVID assessment folder for the positive swab collected at Illness Day 1 on 21Dec2020. There is no COVID folder with this data in the database.' (Site from CRA).		21 Apr 2021 18:34:21
DataPoint Verified.		21 Apr 2021 18:34:08
Query 'Please verify and enter the missing COVID assessment folder for the positive swab collected at Illness Day 1 on 21Dec2020. There is no COVID folder with this data in the database.' answered with 'this folder has been entered ' (Site from CRA).	Jill York (b) (4)	21 Apr 2021 15:04:49
User opened query 'Please verify and enter the missing COVID assessment folder for the positive swab collected at Illness Day 1 on 21Dec2020. There is no COVID folder with this data in the database.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 12:22:58
User closed query 'Please verify and enter all missing COVID, Illness and AE pages for Illness visit positive swab for this subject taken on 21Dec2020' (Site from CRA).		19 Apr 2021 12:22:58
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Query 'Please verify and enter all missing COVID, Illness and AE pages for Illness visit positive swab for this subject taken on 21Dec2020' answered with 'ok' (Site from CRA).	Jill York (b) (4)	07 Apr 2021 21:45:56
User opened query 'Please verify and enter all missing COVID, Illness and AE pages for Illness visit positive swab for this subject taken on 21Dec2020' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 13:25:44
User entered 'Yes (Y)'		23 Feb 2021 18:18:44

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US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
DataPoint Verified.		21 Apr 2021 18:34:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 18:18:44

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
DataPoint Verified.		21 Apr 2021 18:34:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	23 Feb 2021 18:18:44

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'UNBLND_DECIDE'	System	23 Feb 2021 18:18:44

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:00:27
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 18:20:45

FDA-CBER-2022-1614-0084496

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:00:27
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:12:30

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:00:27
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:20:45

FDA-CBER-2022-1614-0084498

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:00:27
Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:12:30

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:00:27
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 18:20:45

FDA-CBER-2022-1614-0084500

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:00:27
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Sponsor Review: Per IRT this subject was randomized to placebo treatment assignment. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 20:19:32
Query 'Sponsor Review: Per IRT this subject was randomized to placebo treatment assignment. Please review and reconcile.' answered with 'subject, since the beginning, has been a placebo' (Site from DM).	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 20:57:56
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 20:56:59
User opened query 'Sponsor Review: Per IRT this subject was randomized to placebo treatment assignment. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:05:01
User entered 'mRNA-1273 (mRNA-1273)'		23 Feb 2021 18:20:45

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:00:27
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	23 Feb 2021 18:20:45

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:00:27
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	23 Feb 2021 18:20:45

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:00:27
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:20:45

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:00:27
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '1'	System	23 Feb 2021 18:20:45

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US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:00:27
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '1'	System	23 Feb 2021 18:20:45

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:00:27
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	23 Feb 2021 18:26:29

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:00:27
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	23 Feb 2021 18:26:29

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:00:27
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered empty.	System	23 Feb 2021 18:26:29
DataPoint set to visible.	System	23 Feb 2021 18:20:45

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:00:27
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	23 Feb 2021 18:26:29

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:00:27
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	23 Feb 2021 18:26:29

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:00:27
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered empty.	System	23 Feb 2021 18:26:29
DataPoint set to visible.	System	23 Feb 2021 18:20:45

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User accepted default value 'Pre-Dose (PREDOSE)'		23 Feb 2021 18:26:29

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:26:29

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US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084515

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '08:26'	(b) (4), (b) (6)	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084516

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '23 Feb 2021 08:26'	System	23 Feb 2021 18:26:29

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	25 Feb 2021 14:03:28
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS. Temporal scanner was used. ' (Site from System).	Jill York (b) (4)	24 Feb 2021 15:51:36
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	23 Feb 2021 18:26:29
User entered '96.6' F	(b) (4), (b) (6)	23 Feb 2021 18:26:29

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Other (Other)'	(b) (4), (b) (6)	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084519

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'temporal'	(b) (4), (b) (6)	23 Feb 2021 18:26:29

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '70'	(b) (4), (b) (6)	23 Feb 2021 18:26:29

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US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'bpm'	System	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084522

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '16'	(b) (4), (b) (6)	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084523

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'breaths/min'	System	23 Feb 2021 18:26:29

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '124'	(b) (4), (b) (6)	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084525

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'mmHg'	System	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084526

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '80'	(b) (4), (b) (6)	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084527

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'mmHg'	System	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084528

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:00:27
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	23 Feb 2021 18:26:29

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:00:27
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	23 Feb 2021 18:26:29

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:00:27
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered empty.	System	23 Feb 2021 18:26:29
DataPoint set to visible.	System	23 Feb 2021 18:20:45

FDA-CBER-2022-1614-0084531

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User accepted default value 'Post-Dose (POSTDOSE)'		23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084532

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084533

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084534

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '09:42'	(b) (4), (b) (6)	23 Feb 2021 18:26:29

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '23 Feb 2021 09:42'	System	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084536

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '97.5' F	(b) (4), (b) (6)	23 Feb 2021 18:26:29

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Other (Other)'	(b) (4), (b) (6)	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084538

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'temporal'	(b) (4), (b) (6)	23 Feb 2021 18:26:29

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '65'	(b) (4), (b) (6)	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084540

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'bpm'	System	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084541

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '16'	(b) (4), (b) (6)	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084542

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'breaths/min'	System	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084543

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '137'	(b) (4), (b) (6)	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084544

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'mmHg'	System	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084545

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '92'	(b) (4), (b) (6)	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084546

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'mmHg'	System	23 Feb 2021 18:26:29

FDA-CBER-2022-1614-0084547

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:27:11

FDA-CBER-2022-1614-0084548

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 18:27:11

FDA-CBER-2022-1614-0084549

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:29:19

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 18:29:19

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
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)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 18:29:19

FDA-CBER-2022-1614-0084552

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'mRNA-1273'	System	23 Feb 2021 18:29:19
DataPoint set to visible.	System	23 Feb 2021 18:20:45

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 18:29:19

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '09:12'	(b) (4), (b) (6)	23 Feb 2021 18:29:19

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '23 Feb 2021 09:12'	System	23 Feb 2021 18:29:19

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	23 Feb 2021 18:29:19

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'ONCE'	System	23 Feb 2021 18:29:19

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered 'INTRAMUSCULAR'	System	23 Feb 2021 18:29:19

FDA-CBER-2022-1614-0084559

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:00:27
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:21:43

FDA-CBER-2022-1614-0084560

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:00:27
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 18:21:43

FDA-CBER-2022-1614-0084561

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:00:27
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '08:17'	(b) (4), (b) (6)	23 Feb 2021 18:21:43

FDA-CBER-2022-1614-0084562

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:00:27
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '23 Feb 2021 08:17'	System	23 Feb 2021 18:21:43

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 11 Aug 2021 22:00:27
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:22:08

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 11 Aug 2021 22:00:27
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 18:22:08

FDA-CBER-2022-1614-0084565

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 11 Aug 2021 22:00:27
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '08:18'	(b) (4), (b) (6)	23 Feb 2021 18:22:08

FDA-CBER-2022-1614-0084566

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 11 Aug 2021 22:00:27
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '23 Feb 2021 08:18'	System	23 Feb 2021 18:22:08

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:22:13

FDA-CBER-2022-1614-0084568

US3142056
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:50:38
User entered '1'	System	23 Feb 2021 18:22:13

US3142056
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:10
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	18 Mar 2021 21:57:04

US3142056
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:10
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '03 Mar 2021'	Lisa Jackson (b) (4) (b) (4)	18 Mar 2021 21:57:04

US3142056
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:10
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Contact Made (CONTACT MADE)'	Lisa Jackson (b) (4) (b) (4)	18 Mar 2021 21:57:04

US3142056
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:10
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	18 Mar 2021 21:57:04

US3142056
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:10
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	18 Mar 2021 21:57:13

US3142056
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:10
User entered '1'	System	18 Mar 2021 21:57:13

US3142056
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:10
User entered '1'	System	18 Mar 2021 21:57:13
DataPoint set to visible.	System	18 Mar 2021 21:57:13

US3142056
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 14:59:41

US3142056
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '01 Apr 2021'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 14:59:41

FDA-CBER-2022-1614-0084578

US3142056
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Clinic (Clinic)'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 14:59:41

US3142056
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:00:27
Folder OID

Audit	User	Time (GMT)
User entered 'OLD29'	System	01 Apr 2021 14:59:41

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:01:26

FDA-CBER-2022-1614-0084581

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:01:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '01 Apr 2021'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:01:26

FDA-CBER-2022-1614-0084583

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '08:29'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:01:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '01 Apr 2021 08:29'	System	01 Apr 2021 15:01:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '97.5' F	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:01:26

FDA-CBER-2022-1614-0084586

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Other (Other)'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:01:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'temporal'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:01:26

FDA-CBER-2022-1614-0084588

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '64'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:01:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Apr 2021 15:01:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '14'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:01:26

FDA-CBER-2022-1614-0084591

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Apr 2021 15:01:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '120'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:01:26

FDA-CBER-2022-1614-0084593

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 15:01:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '79'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:01:26

FDA-CBER-2022-1614-0084595

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 15:01:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:17:26

FDA-CBER-2022-1614-0084597

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:17:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '01 Apr 2021'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:17:26

FDA-CBER-2022-1614-0084599

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '09:20' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:25:33
User entered '09:15'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:17:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '01 Apr 2021 09:20'	System	01 Apr 2021 15:25:33
User entered '01 Apr 2021 09:15'	System	01 Apr 2021 15:17:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '97.3' F reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:25:33
User entered '98.9' F	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:17:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Other (Other)'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:17:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'temporal'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:17:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '57' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:25:33
User entered '59'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:17:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Apr 2021 15:17:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered missing code ND - Not Done.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:17:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Apr 2021 15:17:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '122' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:25:33
User entered '131'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:17:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 15:17:26

US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '81' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:25:33
User entered '83'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:17:26

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US3142056
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:00:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 15:17:26

US3142056
Folder: OL-D29 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:01:55

US3142056
Folder: OL-D29 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:00:27
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '01 Apr 2021'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:01:55

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US3142056
Folder: OL-D29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
Was study treatment given?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:02:36

US3142056
Folder: OL-D29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
If No, reason not given

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:02:36

US3142056
Folder: OL-D29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:02:36

US3142056
Folder: OL-D29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	01 Apr 2021 15:02:36
DataPoint set to visible.	System	18 Mar 2021 21:57:13

US3142056
Folder: OL-D29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '01 Apr 2021'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:02:36

US3142056
Folder: OL-D29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '08:49'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:02:36

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US3142056
Folder: OL-D29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
Treatment Date and Time (derived)

Audit	User	Time (GMT)
User entered '01 Apr 2021 08:49'	System	01 Apr 2021 15:02:36

US3142056
Folder: OL-D29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
Which arm was used to give treatment?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Left Arm (LEFT ARM)'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:02:36

US3142056
Folder: OL-D29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	01 Apr 2021 15:02:36

US3142056
Folder: OL-D29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:00:27
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	01 Apr 2021 15:02:36

US3142056
Folder: OL-D29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:02:45

US3142056
Folder: OL-D29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 15:02:45

US3142056
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'No (N)'	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 20:04:27

US3142056
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 20:04:27

US3142056
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 20:04:27

US3142056
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:00:27
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 20:04:27

US3142056
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 20:04:38

US3142056
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:00:27
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 20:04:38

US3142056
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 11 Aug 2021 22:00:27
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:39:25
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User closed query 'Please enter the COVID/Illness visit assessment in EDC' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:49:13
DataPoint Verified.		21 Apr 2021 17:49:10
Query 'Please enter the COVID/Illness visit assessment in EDC' answered with 'Data has been updated from Source.' (Site from CRA).	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 20:01:19
User opened query 'Please enter the COVID/Illness visit assessment in EDC' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 20:36:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Jill York (b) (4)	26 Mar 2021 03:22:23
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	18 Mar 2021 20:42:16

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US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
AEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:20
User entered 'USA-US064-2021-mRNA-1273-P301000008'		29 Mar 2021 19:38:12
User entered 'New'		29 Mar 2021 19:38:12

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US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User closed query 'Per CDM: Per sponsor review, AE of Covid-19 is reported, however Covid Assessment folder is empty. Please review and update. ' (Site from DM).		19 Apr 2021 13:08:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
Query 'Per CDM: Per sponsor review, AE of Covid-19 is reported, however Covid Assessment folder is empty. Please review and update. ' answered with 'folder added' (Site from DM).	(b) (4) Jill York (b) (4)	09 Apr 2021 21:45:26
User opened query 'Per CDM: Per sponsor review, AE of Covid-19 is reported, however Covid Assessment folder is empty. Please review and update. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:47:40
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Mar 2021 03:26:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Mar 2021 03:26:41
Data point term sent to Coder	System	26 Mar 2021 03:25:52
User entered 'covid-19'	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:38:56
User closed query 'Please verify as per protocol if subject presents for an illness visit it is to be considered an MAAE.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 01:12:00
DataPoint Verified.		21 Apr 2021 01:11:34
Query 'Please verify as per protocol if subject presents for an illness visit it is to be considered an MAAE.' answered with 'changed per query' (Site from CRA).	Jill York (b) (4)	19 Apr 2021 17:59:49
Signature has been broken.	Jill York (b) (4)	19 Apr 2021 17:59:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Jill York (b) (4)	19 Apr 2021 17:59:26
User opened query 'Please verify as per protocol if subject presents for an illness visit it is to be considered an MAAE.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 12:23:42
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'No (N)'	Jill York (b) (4)	26 Mar 2021 03:25:04

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US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'No (N)'	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
User entered 'Yes (Y)'	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '21 Dec 2020'	Jill York (b) (4)	26 Mar 2021 03:25:04

FDA-CBER-2022-1614-0084639

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'No (N)'	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Mar 2021 03:25:41
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	26 Mar 2021 03:25:41
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Mar 2021 03:25:04
User entered '4 Jan 2021'	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	Jill York (b) (4)	26 Mar 2021 03:25:04

FDA-CBER-2022-1614-0084644

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'No (N)'	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
User entered '0'	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
User entered '0'	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '0'	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	Jill York (b) (4)	26 Mar 2021 03:25:04

FDA-CBER-2022-1614-0084651

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	Jill York (b) (4)	26 Mar 2021 03:25:04

FDA-CBER-2022-1614-0084652

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
User entered '0'	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '0'	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '0'	Jill York (b) (4)	26 Mar 2021 03:25:04

FDA-CBER-2022-1614-0084657

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Not Related (NOT RELATED)'	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
User entered 'Not Applicable (NOT APPLICABLE)'	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '1'	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '0'	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '0'	Jill York (b) (4)	26 Mar 2021 03:25:04

FDA-CBER-2022-1614-0084663

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jill York (b) (4)	26 Mar 2021 03:25:41
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:11:34
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'cough, shortness of breath, difficulty breathing, fatigue, body and muscle aches, headache, sore throat, runny nose'	Jill York (b) (4)	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	26 Mar 2021 03:25:04

US3142056
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:00:27
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 17:59:26
User entered '0'	System	26 Mar 2021 03:25:04

US3142056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:00:27

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:39:25
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User closed query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 05:57:06
Query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'subject was contacted and they claimed to have mistakenly checked the box in eDiary ' (Site from DM).	Jill York (b) (4)	23 Mar 2021 17:14:41
User opened query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 10:15:57
User entered 'Yes (Y)'		03 Aug 2020 19:10:40

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:00:27
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 21:16:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 21:16:42
Data point term sent to Coder	System	29 Sep 2020 21:15:38
Coding entries removed.	Jill York (b) (4)	29 Sep 2020 21:15:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 19:14:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 19:14:15
Data point term sent to Coder	System	03 Aug 2020 19:12:30
User entered 'Omeprazole'	(b) (4), (b) (6)	03 Aug 2020 19:12:04

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US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:00:27
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 19:12:04

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:00:27
Indication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User closed query 'Per DM CLR: Please review the indication and spell out the abbreviation as it should not be used. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 16:32:10
Query 'Per DM CLR: Please review the indication and spell out the abbreviation as it should not be used. Please update eCRF as appropriate.' answered with 'done' (Site from DM).	Jill York (b) (4)	29 Sep 2020 21:15:34
User entered 'heartburn' reason for change: Data Entry Error	Jill York (b) (4)	29 Sep 2020 21:15:21
User opened query 'Per DM CLR: Please review the indication and spell out the abbreviation as it should not be used. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 07:51:25
User entered 'GERD'		03 Aug 2020 19:12:04

FDA-CBER-2022-1614-0084672

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:00:27
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '20'	(b) (4), (b) (6)	03 Aug 2020 19:12:04

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:00:27
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Aug 2020 19:12:04

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:00:27
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:12:04

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:00:27
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Aug 2020 19:12:04

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:00:27
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:12:04

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:00:27
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Aug 2020 19:12:04

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:00:27
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:12:04

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:00:27
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 23:12:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 19:12:04
User entered 'un UNK 2000'	(b) (4), (b) (6)	03 Aug 2020 19:12:04

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:00:27
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 19:12:04

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:00:27
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 21:16:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 21:16:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Jill York (b) (4)	29 Sep 2020 21:16:30
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 19:12:04
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:12:04

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US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:00:27
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:12:04

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:00:27
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 19:12:04

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:00:27
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 19:12:04

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:00:27
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 19:12:04

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:00:27
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Aug 2020 19:12:04

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:00:27
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 21:18:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 21:18:44
Data point term sent to Coder	System	29 Sep 2020 21:17:44
Coding entries removed.	Jill York (b) (4)	29 Sep 2020 21:17:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 20:47:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 20:47:57
Data point term sent to Coder	System	03 Aug 2020 19:14:32
User entered 'Vitamin C'	(b) (4), (b) (6)	03 Aug 2020 19:13:38

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:00:27
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 19:13:38

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:00:27
Indication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis this med was prescribed to prevent. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 16:32:18
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis this med was prescribed to prevent. Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM).	Jill York (b) (4)	29 Sep 2020 21:17:11
User entered 'general health' reason for change: Data Entry Error	Jill York (b) (4)	29 Sep 2020 21:17:03
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis this med was prescribed to prevent. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 07:51:54
User entered 'Prophylactic'		03 Aug 2020 19:13:38

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:00:27
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '1000'	(b) (4), (b) (6)	03 Aug 2020 19:13:38

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:00:27
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Aug 2020 19:13:38

FDA-CBER-2022-1614-0084692

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:00:27
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:13:38

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:00:27
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Aug 2020 19:13:38

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:00:27
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:13:38

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:00:27
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Aug 2020 19:13:38

FDA-CBER-2022-1614-0084696

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:00:27
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:13:38

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:00:27
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	03 Aug 2020 23:12:38
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 19:13:38
User entered 'un UNK 2017'	(b) (4), (b) (6)	03 Aug 2020 19:13:38

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:00:27
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 19:13:38

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:00:27
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 19:13:38

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:00:27
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:13:38

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:00:27
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 19:13:38

FDA-CBER-2022-1614-0084702

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:00:27
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 19:13:38

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:00:27
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 19:13:38

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:00:27
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Aug 2020 19:13:38

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:00:27
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 21:18:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 21:18:45
Data point term sent to Coder	System	29 Sep 2020 21:17:45
Coding entries removed.	Jill York (b) (4)	29 Sep 2020 21:17:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 17:29:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 17:29:00
Data point term sent to Coder	System	03 Aug 2020 19:14:33
User entered 'Vitamin D'	(b) (4), (b) (6)	03 Aug 2020 19:14:27

FDA-CBER-2022-1614-0084706

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:00:27
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 19:14:27

FDA-CBER-2022-1614-0084707

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:00:27
Indication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis this med was prescribed to prevent. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 16:32:24
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis this med was prescribed to prevent. Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM).	Jill York (b) (4)	29 Sep 2020 21:17:46
User entered 'general health' reason for change: Data Entry Error	Jill York (b) (4)	29 Sep 2020 21:17:38
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis this med was prescribed to prevent. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 07:52:20
User entered 'Prophylactic'		03 Aug 2020 19:14:27

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:00:27
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '2000'	(b) (4), (b) (6)	03 Aug 2020 19:14:27

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:00:27
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 16:32:32
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'dose is correct per source' (Site from DM).	Jill York (b) (4)	29 Sep 2020 21:18:10
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 07:52:35
User entered 'mg (mg)'		03 Aug 2020 19:14:27

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:00:27
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:14:27

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:00:27
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Aug 2020 19:14:27

FDA-CBER-2022-1614-0084712

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:00:27
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:14:27

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:00:27
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Aug 2020 19:14:27

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:00:27
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:14:27

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:00:27
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	03 Aug 2020 23:12:42
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 19:14:27
User entered 'un UNK 2017'	(b) (4), (b) (6)	03 Aug 2020 19:14:27

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:00:27
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 19:14:27

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:00:27
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 19:14:27

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:00:27
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:14:27

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:00:27
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 19:14:27

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:00:27
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 19:14:27

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:00:27
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 19:14:27

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:00:27
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Aug 2020 19:14:27

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:00:27
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 08:45:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 08:45:10
Data point term sent to Coder	System	29 Sep 2020 21:21:51
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	29 Sep 2020 21:20:51
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'responded' (Site from System).	Jill York (b) (4)	29 Sep 2020 21:20:51
Data point term sent to Coder	System	29 Sep 2020 21:20:49
User entered 'OCUVITE - exact ingredients unknown' reason for change: Data Entry Error	Jill York (b) (4)	29 Sep 2020 21:20:05
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	18 Aug 2020 12:17:17
Data point term sent to Coder	System	03 Aug 2020 19:28:48
User entered 'Ocuvite'	(b) (4), (b) (6)	03 Aug 2020 19:28:02

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:00:27
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 19:28:02

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:00:27
Indication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis this med was prescribed to prevent. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:32:39
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis this med was prescribed to prevent. Update Con Med eCRF as appropriate.' answered with 'done' (Site from DM).	Jill York (b) (4)	29 Sep 2020 21:21:43
User entered 'general eye health' reason for change: Data Entry Error	Jill York (b) (4)	29 Sep 2020 21:21:33
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis this med was prescribed to prevent. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 07:53:01
User entered 'Prophylactic'		03 Aug 2020 19:28:02

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US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:00:27
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '1'	(b) (4), (b) (6)	03 Aug 2020 19:28:02

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:00:27
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	03 Aug 2020 19:28:02

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:00:27
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:28:02

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:00:27
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Aug 2020 19:28:02

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:00:27
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:28:02

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:00:27
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Aug 2020 19:28:02

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:00:27
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Aug 2020 19:28:02

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:00:27
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	03 Aug 2020 23:12:46
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 19:28:02
User entered 'un UNK 2017'	(b) (4), (b) (6)	03 Aug 2020 19:28:02

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:00:27
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 19:28:02

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:00:27
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 19:28:02

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:00:27
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:28:02

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:00:27
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 19:28:02

FDA-CBER-2022-1614-0084738

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:00:27
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 19:28:02

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:00:27
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 19:28:02

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:00:27
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Aug 2020 19:28:02

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:00:27
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 21:24:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 21:24:43
Data point term sent to Coder	System	29 Sep 2020 21:24:00
Coding entries removed.	Jill York (b) (4)	29 Sep 2020 21:23:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 17:29:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 17:29:26
Data point term sent to Coder	System	03 Aug 2020 19:29:50
User entered 'Multivitamin'	(b) (4), (b) (6)	03 Aug 2020 19:29:01

FDA-CBER-2022-1614-0084742

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:00:27
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 19:29:01

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:00:27
Indication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis this med was prescribed to prevent. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:32:45
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis this med was prescribed to prevent. Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM).	Jill York (b) (4)	29 Sep 2020 21:23:28
User entered 'general health' reason for change: Data Entry Error	Jill York (b) (4)	29 Sep 2020 21:23:02
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis this med was prescribed to prevent. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 07:53:19
User entered 'prophylactic'		03 Aug 2020 19:29:01

FDA-CBER-2022-1614-0084744

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:00:27
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '1'	(b) (4), (b) (6)	03 Aug 2020 19:29:01

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:00:27
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	03 Aug 2020 19:29:01

FDA-CBER-2022-1614-0084746

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:00:27
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:29:01

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:00:27
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Aug 2020 19:29:01

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:00:27
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:29:01

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:00:27
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Aug 2020 19:29:01

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:00:27
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:29:01

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:00:27
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	03 Aug 2020 23:12:49
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 19:29:01
User entered 'un UNK 2017'	(b) (4), (b) (6)	03 Aug 2020 19:29:01

FDA-CBER-2022-1614-0084752

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:00:27
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 19:29:01

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:00:27
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 21:23:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 21:23:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Jill York (b) (4)	29 Sep 2020 21:23:02
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 19:29:01
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:29:01

FDA-CBER-2022-1614-0084754

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:00:27
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:29:01

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:00:27
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 19:29:01

FDA-CBER-2022-1614-0084756

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:00:27
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 19:29:01

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:00:27
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 19:29:01

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:00:27
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Aug 2020 19:29:01

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 11 Aug 2021 22:00:27
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: ALLIUM SATIVUM EXTRACT, PRODUCTSYNONYM: GARLIQUE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 13:31:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 13:31:48
Data point term sent to Coder	System	29 Sep 2020 21:25:02
Coding entries removed.	Jill York (b) (4)	29 Sep 2020 21:25:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HERBAL CHOLESTEROL AND TRIGLYCERIDE REDUCERS, PRODUCT: ALLIUM SATIVUM EXTRACT, PRODUCTSYNONYM: GARLIQUE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 14:03:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 14:03:05
Data point term sent to Coder	System	03 Aug 2020 19:30:50
User entered 'Garlique'	(b) (4), (b) (6)	03 Aug 2020 19:30:29

FDA-CBER-2022-1614-0084760

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 11 Aug 2021 22:00:27
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 19:30:29

FDA-CBER-2022-1614-0084761

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 11 Aug 2021 22:00:27
Indication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis this med was prescribed to prevent. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 16:32:50
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis this med was prescribed to prevent. Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM).	Jill York (b) (4)	29 Sep 2020 21:25:11
User entered 'general health' reason for change: Data Entry Error	Jill York (b) (4)	29 Sep 2020 21:25:02
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis this med was prescribed to prevent. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 07:53:37
User entered 'Prophylactic'		03 Aug 2020 19:30:29

FDA-CBER-2022-1614-0084762

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 11 Aug 2021 22:00:27
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Aug 2020 19:34:05
User entered '2'		03 Aug 2020 19:30:29

FDA-CBER-2022-1614-0084763

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 11 Aug 2021 22:00:27
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	03 Aug 2020 19:30:29

FDA-CBER-2022-1614-0084764

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 11 Aug 2021 22:00:27
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:30:29

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 11 Aug 2021 22:00:27
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Aug 2020 19:30:29

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 11 Aug 2021 22:00:27
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:30:29

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 11 Aug 2021 22:00:27
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Aug 2020 19:30:29

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 11 Aug 2021 22:00:27
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:30:29

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 11 Aug 2021 22:00:27
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 23:12:53
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 19:30:29
User entered 'un UNK 2020'	(b) (4), (b) (6)	03 Aug 2020 19:30:29

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 11 Aug 2021 22:00:27
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 19:30:29

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 11 Aug 2021 22:00:27
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 19:30:29

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 11 Aug 2021 22:00:27
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:30:29

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 11 Aug 2021 22:00:27
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 19:30:29

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US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 11 Aug 2021 22:00:27
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 19:30:29

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 11 Aug 2021 22:00:27
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 19:30:29

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 11 Aug 2021 22:00:27
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Aug 2020 19:30:29

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 11 Aug 2021 22:00:27
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: HERBAL DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, PRODUCT: SERENOA REPENS, PRODUCTSYNONYM: SAW PALMETTO [SERENOA REPENS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 21:26:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 21:26:46
Data point term sent to Coder	System	29 Sep 2020 21:26:03
Coding entries removed.	Jill York (b) (4)	29 Sep 2020 21:25:45
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: SERENOA REPENS, PRODUCTSYNONYM: SAW PALMETTO [SERENOA REPENS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 09:01:23
User coded data point as Term Coded data point by User (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 09:01:23
Data point term sent to Coder	System	03 Aug 2020 19:33:52
User entered 'Saw Palmetto'	(b) (4), (b) (6)	03 Aug 2020 19:33:31

FDA-CBER-2022-1614-0084778

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 11 Aug 2021 22:00:27
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 19:33:31

FDA-CBER-2022-1614-0084779

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 11 Aug 2021 22:00:27
Indication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis this med was prescribed to prevent. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:32:55
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis this med was prescribed to prevent. Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM).	Jill York (b) (4)	29 Sep 2020 21:25:58
User entered 'general health' reason for change: Data Entry Error	Jill York (b) (4)	29 Sep 2020 21:25:45
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis this med was prescribed to prevent. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 07:53:58
User entered 'prophylactic'		03 Aug 2020 19:33:31

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 11 Aug 2021 22:00:27
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '2'	(b) (4), (b) (6)	03 Aug 2020 19:33:31

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 11 Aug 2021 22:00:27
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	03 Aug 2020 19:33:31

FDA-CBER-2022-1614-0084782

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 11 Aug 2021 22:00:27
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:33:31

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 11 Aug 2021 22:00:27
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Aug 2020 19:33:31

FDA-CBER-2022-1614-0084784

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 11 Aug 2021 22:00:27
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:33:31

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 11 Aug 2021 22:00:27
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Aug 2020 19:33:31

FDA-CBER-2022-1614-0084786

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 11 Aug 2021 22:00:27
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:33:31

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 11 Aug 2021 22:00:27
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 23:12:57
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 19:33:31
User entered 'un UNK 2017'	(b) (4), (b) (6)	03 Aug 2020 19:33:31

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 11 Aug 2021 22:00:27
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 19:33:31

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 11 Aug 2021 22:00:27
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 19:33:31

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 11 Aug 2021 22:00:27
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 19:33:31

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 11 Aug 2021 22:00:27
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 19:33:31

FDA-CBER-2022-1614-0084792

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 11 Aug 2021 22:00:27
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 19:33:31

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 11 Aug 2021 22:00:27
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 19:33:31

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 11 Aug 2021 22:00:27
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Aug 2020 19:33:31

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 11 Aug 2021 22:00:27
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:19
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 22:46:49
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 22:46:49
Data point term sent to Coder	System	16 Nov 2020 22:46:03
User entered 'tylenol'	Jill York (b) (4)	16 Nov 2020 22:45:52

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 11 Aug 2021 22:00:27
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:19
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'No (N)'	Jill York (b) (4)	16 Nov 2020 22:45:52

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 11 Aug 2021 22:00:27
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:19
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'site injection pain'	Jill York (b) (4)	16 Nov 2020 22:45:52

FDA-CBER-2022-1614-0084798

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 11 Aug 2021 22:00:27
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
User entered '1000'	Jill York (b) (4)	16 Nov 2020 22:45:52

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 11 Aug 2021 22:00:27
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:19
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'mg (mg)'	Jill York (b) (4)	16 Nov 2020 22:45:52

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 11 Aug 2021 22:00:27
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:19
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	Jill York (b) (4)	16 Nov 2020 22:45:52

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 11 Aug 2021 22:00:27
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:19
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'once (ONCE)'	Jill York (b) (4)	16 Nov 2020 22:45:52

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 11 Aug 2021 22:00:27
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:19
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	Jill York (b) (4)	16 Nov 2020 22:45:52

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 11 Aug 2021 22:00:27
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
User entered 'Oral (ORAL)'	Jill York (b) (4)	16 Nov 2020 22:45:52

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 11 Aug 2021 22:00:27
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:19
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered empty.	Jill York (b) (4)	16 Nov 2020 22:45:52

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 11 Aug 2021 22:00:27
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
User entered '5 Aug 2020'	Jill York (b) (4)	16 Nov 2020 22:45:52

FDA-CBER-2022-1614-0084806

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 11 Aug 2021 22:00:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:19
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '0'	Jill York (b) (4)	16 Nov 2020 22:45:52

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 11 Aug 2021 22:00:27
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:26
User entered 'No (N)'	Jill York (b) (4)	16 Nov 2020 22:45:52

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 11 Aug 2021 22:00:27
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:19
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered '5 Aug 2020'	Jill York (b) (4)	16 Nov 2020 22:45:52

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 11 Aug 2021 22:00:27
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:19
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of SITE INJECTION PAIN in eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 04:01:52
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of SITE INJECTION PAIN in eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' answered with 'Subject did not report to the eDiary, but this is the reason that they reported that they took the medication when contacted.' (Site from DM).	Meghan York (b) (4) (b) (4)	21 Jan 2021 16:59:12
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of SITE INJECTION PAIN in eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 15:41:02
User entered 'Yes (Y)'	Jill York (b) (4)	16 Nov 2020 22:45:52

FDA-CBER-2022-1614-0084810

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 11 Aug 2021 22:00:27
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:19
User entered empty.	System	16 Nov 2020 22:45:52

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 11 Aug 2021 22:00:27
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:19
User entered empty.	System	16 Nov 2020 22:45:52

US3142056
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 11 Aug 2021 22:00:27
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:19
User entered empty.	System	16 Nov 2020 22:45:52

US3142056
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 11 Aug 2021 22:00:27
Were any concomitant procedures performed?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:26
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	18 Mar 2021 19:58:32

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'USA-US064-2021-MRNA-1273-P301000008'	System	29 Mar 2021 19:38:12

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'No (N)'	System	29 Mar 2021 19:38:12

FDA-CBER-2022-1614-0084816

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'No (N)'	System	29 Mar 2021 19:38:12

FDA-CBER-2022-1614-0084817

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'No (N)'	System	29 Mar 2021 19:38:12

FDA-CBER-2022-1614-0084818

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'No (N)'	System	29 Mar 2021 19:38:12

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'No (N)'	System	29 Mar 2021 19:38:12

FDA-CBER-2022-1614-0084820

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'No (N)'	System	29 Mar 2021 19:38:12

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'No (N)'	System	29 Mar 2021 19:38:12

FDA-CBER-2022-1614-0084822

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'Ripley'	System	29 Mar 2021 19:38:12

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'Hollister'	System	29 Mar 2021 19:38:12

FDA-CBER-2022-1614-0084824

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered '4190 East Woodmen Road Suite 210'	System	29 Mar 2021 19:38:12

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'Colorado Springs'	System	29 Mar 2021 19:38:12

FDA-CBER-2022-1614-0084826

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered '80920'	System	29 Mar 2021 19:38:12

FDA-CBER-2022-1614-0084827

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'US'	(b) (4) System	29 Mar 2021 19:40:04

FDA-CBER-2022-1614-0084828

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 19:40:04

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'USA-US064-2021-MRNA-1273-P301000008'	System	29 Mar 2021 19:38:12

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'No (N)'	System	29 Mar 2021 19:38:12

FDA-CBER-2022-1614-0084831

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'No (N)'	System	29 Mar 2021 19:38:12

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'No (N)'	System	29 Mar 2021 19:38:12

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'No (N)'	System	29 Mar 2021 19:38:12

FDA-CBER-2022-1614-0084834

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'No (N)'	System	29 Mar 2021 19:38:12

FDA-CBER-2022-1614-0084835

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'No (N)'	System	29 Mar 2021 19:38:12

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'No (N)'	System	29 Mar 2021 19:38:12

FDA-CBER-2022-1614-0084837

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'Ripley'	System	29 Mar 2021 19:38:12

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'Hollister'	System	29 Mar 2021 19:38:12

FDA-CBER-2022-1614-0084839

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered '4190 East Woodmen Road Suite 210'	System	29 Mar 2021 19:38:12

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered 'Colorado Springs'	System	29 Mar 2021 19:38:12

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:39:43
User entered '80920'	System	29 Mar 2021 19:38:12

FDA-CBER-2022-1614-0084842

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered 'US'	(b) (4) System	29 Mar 2021 19:40:04

FDA-CBER-2022-1614-0084843

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:00:27
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 19:40:04

US3142056
Folder: SAE USA-US064-2021-MRNA-1273-P301000008
Form: Safety Report Form (1)
Generated On: 11 Aug 2021 22:00:27
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:13:52
User entered '29/Mar/2021 12:40'	(b) (4) System	29 Mar 2021 19:40:04

US3142056

Folder: SAE USA-US064-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:00:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:13:52
User entered '1'	(b) (4), (b) (6)	29 Mar 2021 19:40:04