US3142013 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:57:08

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US3142013
Form: Participant Creation
Data signed: (b) (4) **18 Apr 2021 18:54:46**
Generated On: 11 Aug 2021 21:57:08

Participant ID	US3142013

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-0073309

US3142013
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	30 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-0073310

US3142013
Folder: Screening
Form: Demographics
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

Date of Birth (MMM yyyy)	(b) (6) 1993
Age	27
Age Units	YEARS
Age (Derived)	27
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

US3142013
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

Date of Informed Consent *(dd MMM yyyy)*	30 JUL 2020
Month and Year of Informed Consent (derived)	JUL 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ■ Amendment 2 ☐ Amendment 3 ☐ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ■ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ■
If Yes, previous participant number	
Enrollment Trigger	1

FDA-CBER-2022-1614-0073312

US3142013
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **18 Apr 2021 18:54:51**
Generated On: 11 Aug 2021 21:57:08

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

US3142013
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-0073314

US3142013
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0073315

US3142013
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

US3142013
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0073317

US3142013
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Condition	PNEUMONIA
Start date (dd MMM yyyy)	UN SEP 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN SEP 2019
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2019
Start Year (derived)	2019
Stop Month and Year (derived)	SEP 2019
Stop Year (derived)	2019

US3142013
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Condition	INGINUAL HERNIA
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)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

US3142013
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Condition	GALLBLADDER DISEASE
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)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

US3142013
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Condition	INTERMITTENT URINARY TRACT INFECTIONS
Start date (dd MMM yyyy)	UN UNK 1994
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

FDA-CBER-2022-1614-0073321

US3142013
Folder: Screening
Form: Medical History (8)
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Condition	INTERMITTENT BENIGN OVARIAN CYSTS
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3142013
Folder: Screening
Form: Medical History (9)
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

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

US3142013
Folder: Screening
Form: Medical History (10)
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Condition	POST-TRAUMATIC STRESS DISORDER
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3142013
Folder: Screening
Form: Medical History (11)
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Condition	INTERMITTENT MARIJUANA USER
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)	

US3142013
Folder: Screening
Form: Medical History (12)
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073326

US3142013
Folder: Screening
Form: Medical History (13)
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073327

US3142013
Folder: Screening
Form: Medical History (14)
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3142013
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Were vital signs assessed?	Yes ☑ No ☐
Date of assessment *(dd MMM yyyy)*	30 JUL 2020
Time of assessment *(00:00-23:59)*	13:37 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 13:37
Height *(xxx.x)*	68 in
Weight *(xxx.x)*	250.0 lb
BMI *(xxx.x)*	38.09185 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)	

US3142013
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **18 Apr 2021 18:55:13**
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Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	30 JUL 2020

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

FDA-CBER-2022-1614-0073330

US3142013
Folder: Screening
Form: Childbearing Potential
Data signed: (b) (4) **18 Apr 2021 18:54:50**
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Date of assessment *(dd MMM yyyy)*	30 JUL 2020
Is the participant of childbearing potential?	Yes ■ No ☐
If No, what is the reason?	Surgically sterile ☐ Post-menopausal ☐ Partner medically sterile ☐ Not reached age of Menarche ☐ Other ☐
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	False

FDA-CBER-2022-1614-0073331

US3142013
Folder: Screening
Form: Pregnancy Test
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Was the pregnancy test performed?	Yes ■ No ☐
Date of test *(dd MMM yyyy)*	30 JUL 2020
Test performed	Urine ■ Serum ☐
Result	Positive ☐ Negative ■
Was FSH sample collected?	Yes ☐ No ■
Collection date	
Collection time	
Collection date and time (derived)	

FDA-CBER-2022-1614-0073332

US3142013
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **18 Apr 2021 18:55:13**
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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

FDA-CBER-2022-1614-0073333

US3142013
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **18 Apr 2021 18:55:13**
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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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

FDA-CBER-2022-1614-0073334

US3142013
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	30 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-0073335

US3142013
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **18 Apr 2021 18:55:13**
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What was the date of randomization? *(dd MMM yyyy)*	30 JUL 2020
What was the participant's randomization number?	142409
In what Cohort was the participant enrolled?	>=18 and <65 years and not at risk ☐ >=18 and <65 years and at risk ■ >=65 years ☐

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

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

FDA-CBER-2022-1614-0073336

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-0073337

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

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)*	30 JUL 2020
Time of assessment *(00:00-23:59)*	13:37 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 13:37
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	89 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	77 mmHg
Diastolic Blood Pressure units	MMHG

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

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)*	30 JUL 2020
Time of assessment *(00:00-23:59)*	15:20 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 15:20
Temperature *(xxx.x)*	99.1 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	80 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	84 mmHg
Diastolic Blood Pressure units	MMHG

US3142013
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	30 JUL 2020

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

FDA-CBER-2022-1614-0073340

US3142013
Folder: Visit 1 Day 1
Form: Pregnancy Test
Data signed: (b) (4) **18 Apr 2021 18:55:13**
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Was the pregnancy test performed?	Yes ☐ No ■
Date of test *(dd MMM yyyy)*	
Test performed	Urine ☐ Serum ☐
Result	Positive ☐ Negative ☐
Was FSH sample collected?	Yes ☐ No ■
Collection date	
Collection time	
Collection date and time (derived)	

FDA-CBER-2022-1614-0073341

US3142013
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **18 Apr 2021 18:55:13**
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Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	30 JUL 2020
What was the treatment time? *(00:00-23:59)*	14:50 (24 HR)
Treatment Date and Time (derived)	30 JUL 2020 14:50
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3142013
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	30 JUL 2020
Collection time *(00:00-23:59)*	14:19 (24 HR)
Collection date and time (derived)	30 JUL 2020 14:19

US3142013
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Collection date *(dd MMM yyyy)*			30 JUL 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:19	30 JUL 2020 14:19
Nasopharyngeal Swab 2	Yes	14:19	30 JUL 2020 14:19

FDA-CBER-2022-1614-0073344

US3142013
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 18:55:13**
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Is the participant continuing to the next visit?	Yes ☑ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0073345

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:57:08

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	30 JUL 2020 15:10
PC Close Date & Time	30 JUL 2020 17:40

FDA-CBER-2022-1614-0073346

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:57:08

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	30 JUL 2020 18:35
PC Close Date & Time	31 JUL 2020 11:59

FDA-CBER-2022-1614-0073347

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	01 AUG 2020 09:43
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

FDA-CBER-2022-1614-0073348

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.6 °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	01 AUG 2020 12:01
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

FDA-CBER-2022-1614-0073349

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.4 °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	02 AUG 2020 21:29
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

FDA-CBER-2022-1614-0073350

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073351

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.7 °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 12:18
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

FDA-CBER-2022-1614-0073352

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	05 AUG 2020 13:01
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

FDA-CBER-2022-1614-0073353

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:57:08

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	30 JUL 2020 15:10
PC Close Date & Time	30 JUL 2020 17:40

FDA-CBER-2022-1614-0073354

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:57:08

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	30 JUL 2020 18:35
PC Close Date & Time	31 JUL 2020 11:59

FDA-CBER-2022-1614-0073355

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:57:08

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	01 AUG 2020 09:42
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073357

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:57:08

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

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073359

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:57:08

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	04 AUG 2020 12:18
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

FDA-CBER-2022-1614-0073360

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:57:08

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	05 AUG 2020 13:00
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 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-2022-1614-0073362

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	30 JUL 2020 15:10
PC Close Date & Time	30 JUL 2020 17:40

FDA-CBER-2022-1614-0073363

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-2022-1614-0073364

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	30 JUL 2020 18:35
PC Close Date & Time	31 JUL 2020 11:59

FDA-CBER-2022-1614-0073365

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073366

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08

	Yes ☐
PC Time stamp	01 AUG 2020 09:42
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073368

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08

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

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073370

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073371

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073372

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073373

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073374

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08

	Yes ☐
PC Time stamp	04 AUG 2020 12:17
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

FDA-CBER-2022-1614-0073375

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073376

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08

	Yes ☐
PC Time stamp	05 AUG 2020 13:00
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

FDA-CBER-2022-1614-0073377

US3142013
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **HEADACHE**	None ☐ No interference with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or some interfererence with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	07 AUG 2020 09:35
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

FDA-CBER-2022-1614-0073378

US3142013
Folder: Diary Dose 1 (1)
Form: Headache_Day(9)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 9
Select one response below to indicate the intensity of your **HEADACHE**	None ☐ No interference with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or some interfererence with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	07 AUG 2020 12:00
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

FDA-CBER-2022-1614-0073379

US3142013
Folder: Diary Dose 1 (1)
Form: Headache_Day(10)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 10
Select one response below to indicate the intensity of your **HEADACHE**	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interfererence with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	08 AUG 2020 12:02
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

FDA-CBER-2022-1614-0073380

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	07 AUG 2020 09:35
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

FDA-CBER-2022-1614-0073381

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 9
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	07 AUG 2020 12:00
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

FDA-CBER-2022-1614-0073382

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(10)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 10
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	08 AUG 2020 12:02
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

FDA-CBER-2022-1614-0073383

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(11)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 11
Select one response below to indicate the intensity of your **FATIGUE**	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	09 AUG 2020 17:32
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

FDA-CBER-2022-1614-0073384

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	07 AUG 2020 09:35
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

FDA-CBER-2022-1614-0073385

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 9
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	07 AUG 2020 12:00
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 10
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	08 AUG 2020 12:02
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

FDA-CBER-2022-1614-0073387

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 11
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	09 AUG 2020 17:32
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

FDA-CBER-2022-1614-0073388

US3142013
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	7 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-2022-1614-0073389

US3142013
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073390

US3142013
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073391

US3142013
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073392

US3142013
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073393

US3142013
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

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

US3142013
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

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	VISIT2

FDA-CBER-2022-1614-0073395

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	29 SEP 2020
Time of assessment *(00:00-23:59)*	16:40 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 16:40
Temperature *(xxx.x)*	97.3 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	86 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)*	90 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0073396

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	29 SEP 2020
Time of assessment *(00:00-23:59)*	17:33 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 17:33
Temperature *(xxx.x)*	97.6 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)*	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	84 mmHg
Diastolic Blood Pressure units	MMHG

US3142013
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073398

US3142013
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Was the pregnancy test performed?	Yes ■ No ☐
Date of test *(dd MMM yyyy)*	29 SEP 2020
Test performed	Urine ■ Serum ☐
Result	Positive ☐ Negative ■
Was FSH sample collected?	Yes ☐ No ■
Collection date	
Collection time	
Collection date and time (derived)	

US3142013
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

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)*	29 SEP 2020
What was the treatment time? *(00:00-23:59)*	17:03 (24 HR)
Treatment Date and Time (derived)	29 SEP 2020 17:03
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

US3142013
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	29 SEP 2020
Collection time *(00:00-23:59)*	16:54 (24 HR)
Collection date and time (derived)	29 SEP 2020 16:54

US3142013
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Collection date *(dd MMM yyyy)*			29 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:46	29 SEP 2020 16:46
Nasopharyngeal Swab 2	Yes	16:46	29 SEP 2020 16:46

FDA-CBER-2022-1614-0073402

US3142013
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073403

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:57:08

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	29 SEP 2020 18:29
PC Open Date & Time	29 SEP 2020 17:23
PC Close Date & Time	29 SEP 2020 19:53

FDA-CBER-2022-1614-0073404

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.6 °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	30 SEP 2020 10:28
PC Open Date & Time	29 SEP 2020 20:48
PC Close Date & Time	30 SEP 2020 11:59

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	30 SEP 2020 12:29
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

FDA-CBER-2022-1614-0073406

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.6 °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	01 OCT 2020 12:00
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.4 °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	03 OCT 2020 08:06
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

FDA-CBER-2022-1614-0073408

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.4 °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	04 OCT 2020 09:35
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

FDA-CBER-2022-1614-0073409

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:57:08

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	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

FDA-CBER-2022-1614-0073410

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:57:08

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	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

FDA-CBER-2022-1614-0073411

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:57:08

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	29 SEP 2020 18:29
PC Open Date & Time	29 SEP 2020 17:23
PC Close Date & Time	29 SEP 2020 19:53

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:57:08

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	30 SEP 2020 10:29
PC Open Date & Time	29 SEP 2020 20:48
PC Close Date & Time	30 SEP 2020 11:59

FDA-CBER-2022-1614-0073413

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:57:08

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	30 SEP 2020 12:29
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:57:08

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

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:57:08

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	03 OCT 2020 08:06
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:57:08

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	04 OCT 2020 09:35
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:57:08

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	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

FDA-CBER-2022-1614-0073418

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:57:08

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	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

FDA-CBER-2022-1614-0073419

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-2022-1614-0073420

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ◉ Yes ○
PC Time stamp	29 SEP 2020 18:29
PC Open Date & Time	29 SEP 2020 17:23
PC Close Date & Time	29 SEP 2020 19:53

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-2022-1614-0073422

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☑ Yes ☐
PC Time stamp	30 SEP 2020 10:28
PC Open Date & Time	29 SEP 2020 20:48
PC Close Date & Time	30 SEP 2020 11:59

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073424

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08

	Yes ☐
PC Time stamp	30 SEP 2020 12:30
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

FDA-CBER-2022-1614-0073425

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073426

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08

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

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073428

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08

	Yes ☐
PC Time stamp	03 OCT 2020 08:06
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

FDA-CBER-2022-1614-0073429

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073430

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08

	Yes ☐
PC Time stamp	04 OCT 2020 09:35
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073432

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073433

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073434

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08

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

US3142013
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	9 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-2022-1614-0073436

US3142013
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073437

US3142013
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	13 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-2022-1614-0073438

US3142013
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073439

US3142013
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	26 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-2022-1614-0073440

US3142013
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073441

US3142013
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	30 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT3

FDA-CBER-2022-1614-0073442

US3142013
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	30 OCT 2020
Time of assessment *(00:00-23:59)*	09:08 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 09:08
Temperature *(xxx.x)*	97.2 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	94 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142013
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	30 OCT 2020

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

FDA-CBER-2022-1614-0073444

US3142013
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	30 OCT 2020
Collection time *(00:00-23:59)*	9:24 (24 HR)
Collection date and time (derived)	30 OCT 2020 9:24

FDA-CBER-2022-1614-0073445

US3142013
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 18:55:13**
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073446

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 SEP 2020 18:28:42
Patient Cloud Open Date & Time	29 SEP 2020 00:01
Patient Cloud Close Date & Time	03 OCT 2020 23:59

FDA-CBER-2022-1614-0073447

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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 ☐

FDA-CBER-2022-1614-0073448

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have 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-2022-1614-0073452

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

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have 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-2022-1614-0073454

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

FDA-CBER-2022-1614-0073455

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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 ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have 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-2022-1614-0073456

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

FDA-CBER-2022-1614-0073457

TIMEPOINT	DAY 113
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have 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-2022-1614-0073458

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

FDA-CBER-2022-1614-0073459

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

FDA-CBER-2022-1614-0073460

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073462

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

FDA-CBER-2022-1614-0073463

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073464

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0073466

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

FDA-CBER-2022-1614-0073467

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073470

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

FDA-CBER-2022-1614-0073471

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073472

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0073474

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073476

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073477

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0073478

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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

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

FDA-CBER-2022-1614-0073482

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

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0073484

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

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0073486

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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

US3142013
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073488

US3142013
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	20 NOV 2020
Please select one status for the follow-up contact	Contact Made ☐ Contact Not Made ■
Comments	LEFT MESSAGE

If Contact Not Made, please provide Comments

FDA-CBER-2022-1614-0073489

US3142013
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073490

US3142013
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073491

US3142013
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073492

US3142013
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	3 FEB 2021
Please select one status for the follow-up contact	Contact Made ☐ Contact Not Made ■
Comments	VOICE MAIL NOT SET UP

If Contact Not Made, please provide Comments

FDA-CBER-2022-1614-0073493

US3142013
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073494

US3142013
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	26 FEB 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-0073495

US3142013
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **18 Apr 2021 18:54:50**
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073496

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: COVID-19 Contact
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

Date of Contact	19 AUG 2020
Time of Contact	13:40
Date and Time of Contact (derived)	19 AUG 2020 13:40
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-2022-1614-0073497

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073498

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	19 AUG 2020
Assessment Not Done	False
O2 Saturation	91 %
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 ☐

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

	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-2022-1614-0073500

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-2022-1614-0073501

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073502

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	20 AUG 2020
Assessment Not Done	False
O2 Saturation	95 %
O2 Saturation Units	%
Temperature	99.8 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 ☐

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

	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-2022-1614-0073504

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-2022-1614-0073505

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073506

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	21 AUG 2020
Assessment Not Done	False
O2 Saturation	95 %
O2 Saturation Units	%
Temperature	99.1 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 ☐

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

	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-2022-1614-0073509

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073510

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	22 AUG 2020
Assessment Not Done	False
O2 Saturation	95 %
O2 Saturation Units	%
Temperature	99.6 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

	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 ☐

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073514

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	23 AUG 2020
Assessment Not Done	False
O2 Saturation	95 %
O2 Saturation Units	%
Temperature	99.3 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 ☐

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

	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-2022-1614-0073517

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073518

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	24 AUG 2020
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	99.5 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 ☐

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

	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-2022-1614-0073521

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: COVID Diagnostic Test
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

Date of Visit	19 AUG 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	19 AUG 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

FDA-CBER-2022-1614-0073522

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Generate Next COVID-19 Assessment
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

Generate Next COVID-19 Assessment	Yes ■ No ☐

FDA-CBER-2022-1614-0073523

US3142013
Folder: Covid-19 Assessment 24 Aug 2020
Form: Generate Next COVID-19 Assessment
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

Generate Next COVID-19 Assessment	Yes ☐ No ■

FDA-CBER-2022-1614-0073524

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: COVID-19 Contact
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

Date of Contact	30 OCT 2020
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐ Clinical Visit - Unscheduled ■ Safety Call ☐ Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ■ No ☐

FDA-CBER-2022-1614-0073525

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073526

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	28 OCT 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 ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

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	29 OCT 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 ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

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
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- [ ] Day 25
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- [ ] Day 27
- [ ] Day 28
- [ ] Day 29
- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-0073534

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	30 OCT 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 ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

	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-2022-1614-0073537

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073538

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	31 OCT 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 ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

	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 ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073542

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	01 NOV 2020
Assessment Not Done	False
O2 Saturation	90 %
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 ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

	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-2022-1614-0073544

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 ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073546

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	02 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 ☐

	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 ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073550

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	03 NOV 2020
Assessment Not Done	False
O2 Saturation	93 %
O2 Saturation Units	%
Temperature	98.1 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ☐ Mild ■ Moderate ☐ Severe ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

	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-2022-1614-0073553

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073554

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	04 NOV 2020
Assessment Not Done	False
O2 Saturation	93 %
O2 Saturation Units	%
Temperature	99.8 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 ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

	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-2022-1614-0073557

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-2022-1614-0073558

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	05 NOV 2020
Assessment Not Done	False
O2 Saturation	94 %
O2 Saturation Units	%
Temperature	99.3 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 ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

	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-2022-1614-0073561

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-2022-1614-0073562

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	06 NOV 2020
Assessment Not Done	False
O2 Saturation	93 %
O2 Saturation Units	%
Temperature	98.9 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 ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

	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-2022-1614-0073565

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-2022-1614-0073566

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	07 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 ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

	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-2022-1614-0073568

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-2022-1614-0073570

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	08 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 ☐

	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-2022-1614-0073574

	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 ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

	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-2022-1614-0073576

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-2022-1614-0073578

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	10 NOV 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	98.8 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 ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

	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-2022-1614-0073581

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

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
- [x] 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-2022-1614-0073582

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	11 NOV 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	98.7 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

	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-2022-1614-0073586

	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	99.0 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

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

Nasal Congestion	None ☐ Mild ■ Moderate ☐ 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-2022-1614-0073590

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	13 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 ☐

	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-2022-1614-0073594

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	14 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 ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

	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-2022-1614-0073596

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 ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

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
- [x] 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-2022-1614-0073598

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	15 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 ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

	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	16 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 ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

	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 ☐

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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-2022-1614-0073606

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	17 NOV 2020
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	97.8 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 ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

	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-2022-1614-0073609

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-2022-1614-0073610

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	20 NOV 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	98.2 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Data signed: (b) (4) **18 Apr 2021 18:54:48**
Generated On: 11 Aug 2021 21:57:08

	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-2022-1614-0073613

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: COVID Diagnostic Test
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

Date of Visit	30 OCT 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	30 OCT 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-2022-1614-0073614

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	01 NOV 2020
End Date	04 NOV 2020
Oxygen Saturation	90 %
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	

FDA-CBER-2022-1614-0073616

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	

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Generate Next COVID-19 Assessment
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

Generate Next COVID-19 Assessment	Yes ☐ No ■

FDA-CBER-2022-1614-0073618

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection
Data signed: (b) (4) **18 Apr 2021 18:54:49**
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073619

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection
Data signed: (b) (4) **18 Apr 2021 18:54:49**
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073620

US3142013
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Data signed: (b) (4) **18 Apr 2021 18:54:49**
Generated On: 11 Aug 2021 21:57:08

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SICKD1

FDA-CBER-2022-1614-0073621

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Data signed: (b) (4) **18 Apr 2021 18:54:49**
Generated On: 11 Aug 2021 21:57:08

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	19 AUG 2020
Time of assessment *(00:00-23:59)*	13:41 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 13:41
Height *(xxx.x)*	68 in
Weight *(xxx.x)*	ND - Not Done
Temperature *(xxx.x)*	97.0 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	96 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142013
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Data signed: (b) (4) **18 Apr 2021 18:54:49**
Generated On: 11 Aug 2021 21:57:08

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	19 AUG 2020

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

FDA-CBER-2022-1614-0073623

US3142013
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 18:54:49**
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073624

US3142013
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Data signed: (b) (4) **18 Apr 2021 18:54:49**
Generated On: 11 Aug 2021 21:57:08

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	30 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	SICKD1

FDA-CBER-2022-1614-0073625

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Data signed: (b) (4) **18 Apr 2021 18:54:49**
Generated On: 11 Aug 2021 21:57:08

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	30 OCT 2020
Time of assessment *(00:00-23:59)*	09:08 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 09:08
Height *(xxx.x)*	ND - Not Done
Weight *(xxx.x)*	ND - Not Done
Temperature *(xxx.x)*	97.2 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	94 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0073626

US3142013
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Data signed: (b) (4) **18 Apr 2021 18:54:49**
Generated On: 11 Aug 2021 21:57:08

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	30 OCT 2020

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

FDA-CBER-2022-1614-0073627

US3142013
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 18:54:49**
Generated On: 11 Aug 2021 21:57:08

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ■ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	30 OCT 2020

FDA-CBER-2022-1614-0073628

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073629

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

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)	

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

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.

US3142013
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 18:54:47**
Generated On: 11 Aug 2021 21:57:08

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

US3142013
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08

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-2022-1614-0073633

US3142013
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 21:57:08

Date of updated informed consent *(dd MMM yyyy)*	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	
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)*	
Participant randomization assignment	mRNA-1273 ☐ Placebo ☐
Actual Dose 1	mRNA-1273 ☐ Placebo ☐ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ☐ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☐ No ☐
Placebo Only Flag	
Continuing with mRNA-1273	

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

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

US3142013
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

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

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-0073637

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **18 Apr 2021 18:54:46**
Generated On: 11 Aug 2021 21:57:08

AEID	USA-US064-2020-MRNA-1273-P30 1000004
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)*	28 OCT 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	17 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ■ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

FDA-CBER-2022-1614-0073638

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **18 Apr 2021 18:54:46**
Generated On: 11 Aug 2021 21:57:08

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

	SUBJECT PRESENTED WITH THE FOLLOWING MILD SYMPTOMS: COUGH, SHORTNESS OF BREATH, CONGESTION, AND CHILLS. SUBJECT ALSO REPORTED THE FOLLOWING MODERATE SYMPTOMS: FATIGUE, MUSCLE/BODY ACHES, HEADACHE, SORE THROAT, DIARRHEA
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **18 Apr 2021 18:54:46**
Generated On: 11 Aug 2021 21:57:08

AEID	
Adverse event	FATIGUE PERSISTING PAST 7 DAYS
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)*	31 JUL 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	8 AUG 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ■ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

FDA-CBER-2022-1614-0073641

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **18 Apr 2021 18:54:46**
Generated On: 11 Aug 2021 21:57:08

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	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Data signed: (b) (4) **18 Apr 2021 18:54:46**
Generated On: 11 Aug 2021 21:57:08

AEID	
Adverse event	HEADACHE PERSISTING PAST 7 DAYS
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)*	2 AUG 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	7 AUG 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ■ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Data signed: (b) (4) **18 Apr 2021 18:54:46**
Generated On: 11 Aug 2021 21:57:08

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	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

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

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

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

Name of Medication	SYMBICORT
Prophylaxis	Yes ☐ No ■
Indication	ASTHMA
Dose per administration	80/4.5
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	MCG
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-0073646

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

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

Name of Medication	SINGULAIR
Prophylaxis	Yes ☐ No ■
Indication	ASTHMA
Dose per administration	10
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-0073648

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

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

Name of Medication	ZOLOFT
Prophylaxis	Yes ☐ No ■
Indication	POST TRAUMATIC STRESS DISORDER
Dose per administration	200
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 2019
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

Name of Medication	HYDROXYZINE
Prophylaxis	Yes ☐ No ■
Indication	ANXIETY
Dose per administration	50
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-2022-1614-0073652

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

Name of Medication	NYQUIL (ACETAMINOPHEN 650MG/ DEXTROMETHORPHAN HBR 30MG/ DOXYLAMINE 12.5 MG)
Prophylaxis	Yes ☐ No ■
Indication	HEADACHE
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	TABLESPOONS
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)*	30 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	30 SEP 2020
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 ■

US3142013
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **18 Apr 2021 18:54:47**
Generated On: 11 Aug 2021 21:57:08

Were any concomitant procedures performed?	Yes ☐
	No ■

If yes, please complete Concomitant Procedures form.

US3142013
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 11 Aug 2021 21:57:08

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

FDA-CBER-2022-1614-0073657

US3142013
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **18 Apr 2021 18:54:49**
Generated On: 11 Aug 2021 21:57:08

Date of study discontinuation/completion *(dd MMM yyyy)*	26 FEB 2021
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-2022-1614-0073658

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Data signed: (b) (4) **18 Apr 2021 18:54:49**
Generated On: 11 Aug 2021 21:57:08

SAEID	USA-US064-2020-MRNA-1273-P301000004
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)	3

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form (1)
Data signed: (b) (4) **18 Apr 2021 18:54:49**
Generated On: 11 Aug 2021 21:57:08

SAEID	USA-US064-2020-MRNA-1273-P301000004
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)	3
Date of submission (Pre-filled from custom function)	13/NOV/2020 21:46
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

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form (2)
Data signed: (b) (4) **18 Apr 2021 18:54:49**
Generated On: 11 Aug 2021 21:57:08

SAEID	USA-US064-2020-MRNA-1273-P301000004
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)	3
Date of submission (Pre-filled from custom function)	30/NOV/2020 01:47
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

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form (3)
Data signed: (b) (4) **18 Apr 2021 18:54:49**
Generated On: 11 Aug 2021 21:57:08

SAEID	USA-US064-2020-MRNA-1273-P301000004
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)	3
Date of submission (Pre-filled from custom function)	31/MAR/2021 11:54
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3142013 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

FDA-CBER-2022-1614-0073663

US3142013
Form: Participant Creation
Generated On: 11 Aug 2021 21:57:08
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'US3142013'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 18:54:29

FDA-CBER-2022-1614-0073664

US3142013
Form: Participant Creation
Generated On: 11 Aug 2021 21:57:08

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0073665

US3142013
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:36:43

US3142013
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '30 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 18:54:30

FDA-CBER-2022-1614-0073667

US3142013
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:36:43

US3142013
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'SCRN'	System	30 Jul 2020 20:36:43

FDA-CBER-2022-1614-0073669

US3142013
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:57:08
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered (b) (6) 1993'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 18:54:31

FDA-CBER-2022-1614-0073670

US3142013
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:57:08
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '27'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:15:29

US3142013
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:57:08
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'YEARS'	System	04 Aug 2020 01:15:29

US3142013
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:57:08
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '27'	System	30 Jul 2020 20:37:05

US3142013
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:57:08
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Female (F)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:15:29

US3142013
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:57:08
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:15:29

US3142013
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:57:08
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '1'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:15:29

US3142013
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:57:08
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:15:29

US3142013
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:57:08
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:15:29

US3142013
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:57:08
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:15:29

US3142013
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:57:08
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:15:29

US3142013
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:57:08
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:15:29

US3142013
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:57:08
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:15:29

US3142013
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:57:08
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:15:29

US3142013
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:57:08
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:15:29

US3142013
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:57:08
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '30 Jul 2020'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:37:05

US3142013
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:57:08
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'Jul 2020'	System	30 Jul 2020 20:37:05

US3142013
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:57:08
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '2020'	System	30 Jul 2020 20:37:05

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US3142013
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:57:08
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Amendment 1 (1)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:37:05

US3142013
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:57:08
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:37:05

US3142013
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:57:08
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:37:05

US3142013
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:57:08
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:37:05

US3142013
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:57:08
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:37:05

US3142013
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:57:08
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 18:54:30

US3142013
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:57:08
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1'	System	30 Jul 2020 20:37:12

US3142013
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 11 Aug 2021 21:57:08
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:37:12

US3142013
Folder: Screening
Form: Medical History Summary
Generated On: 11 Aug 2021 21:57:08
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:15:40

US3142013
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 21:57:08
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
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)	04 Aug 2020 01:18:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:18:06
Data point term sent to Coder	System	04 Aug 2020 01:17:23
User entered 'Seasonal Allergies'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:16:27

US3142013
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 21:57:08
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'UN UNK 2005'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:16:27

US3142013
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 21:57:08
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:16:27

US3142013
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 21:57:08
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:16:27

US3142013
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 21:57:08
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:16:27

US3142013
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 21:57:08
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:16:27

US3142013
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 21:57:08
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'Jan 2005'	System	04 Aug 2020 01:16:27

US3142013
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 21:57:08
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '2005'	System	04 Aug 2020 01:16:27

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US3142013
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 21:57:08
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:16:27

US3142013
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 21:57:08
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:16:27

FDA-CBER-2022-1614-0073706

US3142013
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 21:57:08
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:18:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:18:06
Data point term sent to Coder	System	04 Aug 2020 01:17:23
User entered 'Tonsillitis'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:17:02

US3142013
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 21:57:08
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'UN UNK 2009'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:17:02

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US3142013
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 21:57:08
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:17:02

US3142013
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 21:57:08
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:17:02

US3142013
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 21:57:08
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'UN UNK 2009'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:17:02

US3142013
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 21:57:08
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:17:02

US3142013
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 21:57:08
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'Jan 2009'	System	04 Aug 2020 01:17:02

US3142013
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 21:57:08
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '2009'	System	04 Aug 2020 01:17:02

FDA-CBER-2022-1614-0073714

US3142013
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 21:57:08
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'Jan 2009'	System	04 Aug 2020 01:17:02

US3142013
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 21:57:08
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '2009'	System	04 Aug 2020 01:17:02

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US3142013
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 21:57:08
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
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)	04 Aug 2020 01:19:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:19:07
Data point term sent to Coder	System	04 Aug 2020 01:18:24
User entered 'Asthma'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:17:25

US3142013
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 21:57:08
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'UN UNK 2017'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:17:25

US3142013
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 21:57:08
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:17:25

US3142013
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 21:57:08
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:17:25

US3142013
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 21:57:08
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:17:25

US3142013
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 21:57:08
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:17:25

US3142013
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 21:57:08
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'Jan 2017'	System	04 Aug 2020 01:17:25

US3142013
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 21:57:08
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '2017'	System	04 Aug 2020 01:17:25

FDA-CBER-2022-1614-0073724

US3142013
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 21:57:08
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:17:25

US3142013
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 21:57:08
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:17:25

FDA-CBER-2022-1614-0073726

US3142013
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 21:57:08
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:20:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:20:07
Data point term sent to Coder	System	04 Aug 2020 01:19:26
User entered 'Pneumonia'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:19:13

US3142013
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 21:57:08
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'UN Sep 2019'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:19:13

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US3142013
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 21:57:08
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:19:13

US3142013
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 21:57:08
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:19:13

US3142013
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 21:57:08
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'UN Sep 2019'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:19:13

US3142013
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 21:57:08
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:19:13

US3142013
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 21:57:08
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'Sep 2019'	System	04 Aug 2020 01:19:13

US3142013
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 21:57:08
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '2019'	System	04 Aug 2020 01:19:13

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US3142013
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 21:57:08
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'Sep 2019'	System	04 Aug 2020 01:19:13

US3142013
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 21:57:08
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '2019'	System	04 Aug 2020 01:19:13

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US3142013
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 21:57:08
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 14:10:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 14:10:05
Data point term sent to Coder	System	04 Aug 2020 01:20:27
User entered 'Inginual Hernia'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:20:06

US3142013
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 21:57:08
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'UN UNK 2013'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:20:06

US3142013
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 21:57:08
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:20:06

US3142013
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 21:57:08
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:20:06

US3142013
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 21:57:08
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'UN UNK 2013'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:20:06

US3142013
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 21:57:08
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:20:06

US3142013
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 21:57:08
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'Jan 2013'	System	04 Aug 2020 01:20:06

US3142013
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 21:57:08
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '2013'	System	04 Aug 2020 01:20:06

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US3142013
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 21:57:08
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'Jan 2013'	System	04 Aug 2020 01:20:06

US3142013
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 21:57:08
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '2013'	System	04 Aug 2020 01:20:06

FDA-CBER-2022-1614-0073746

US3142013
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 21:57:08
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Gallbladder disorders NEC, PT: Gallbladder disorder, LLT: Gallbladder disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:22:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:22:09
Data point term sent to Coder	System	04 Aug 2020 01:21:28
User entered 'Gallbladder Disease'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:20:33

US3142013
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 21:57:08
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'UN UNK 2013'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:20:33

US3142013
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 21:57:08
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:20:33

US3142013
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 21:57:08
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:20:33

US3142013
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 21:57:08
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'UN UNK 2013'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:20:33

FDA-CBER-2022-1614-0073751

US3142013
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 21:57:08
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:20:33

US3142013
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 21:57:08
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'Jan 2013'	System	04 Aug 2020 01:20:33

US3142013
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 21:57:08
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '2013'	System	04 Aug 2020 01:20:33

FDA-CBER-2022-1614-0073754

US3142013
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 21:57:08
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'Jan 2013'	System	04 Aug 2020 01:20:33

US3142013
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 21:57:08
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '2013'	System	04 Aug 2020 01:20:33

FDA-CBER-2022-1614-0073756

US3142013
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 21:57:08
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Recurrent urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 13:38:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 13:38:00
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 14:13:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 14:13:06
Data point term sent to Coder	System	04 Aug 2020 01:21:28
User entered 'Intermittent Urinary Tract Infections'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:21:06

US3142013
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 21:57:08
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'UN UNK 1994'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:21:06

FDA-CBER-2022-1614-0073758

US3142013
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 21:57:08
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:21:06

US3142013
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 21:57:08
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:21:06

US3142013
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 21:57:08
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'UN UNK 1999'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:21:06

US3142013
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 21:57:08
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:21:06

US3142013
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 21:57:08
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'Jan 1994'	System	04 Aug 2020 01:21:06

US3142013
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 21:57:08
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1994'	System	04 Aug 2020 01:21:06

FDA-CBER-2022-1614-0073764

US3142013
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 21:57:08
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'Jan 1999'	System	04 Aug 2020 01:21:06

US3142013
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 21:57:08
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1999'	System	04 Aug 2020 01:21:06

FDA-CBER-2022-1614-0073766

US3142013
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 21:57:08
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User closed query 'Per DM CLR: Please update the condition to confirm if the CYST was benign or cancerous. Review and update medical history as appropriate. Ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 15:22:21
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Benign ovarian cyst - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 22:22:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 22:22:41
Data point term sent to Coder	System	29 Sep 2020 17:23:47
Query 'Per DM CLR: Please update the condition to confirm if the CYST was benign or cancerous. Review and update medical history as appropriate. 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)	29 Sep 2020 17:23:24
Coding entries removed.	Meghan York (b) (4) (b) (4)	29 Sep 2020 17:23:20
User entered 'INTERMITTENT benign OVARIAN CYSTS' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	29 Sep 2020 17:23:20
User opened query 'Per DM CLR: Please update the condition to confirm if the CYST was benign or cancerous. Review and update medical history as appropriate. 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 06:09:07
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Ovarian cyst - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:24:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:24:13
Data point term sent to Coder	System	04 Aug 2020 01:22:28

US3142013
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 21:57:08
Condition

Audit	User	Time (GMT)
User entered 'Intermittent Ovarian Cysts'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:21:28

US3142013
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 21:57:08
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'UN UNK 2010'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:21:28

US3142013
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 21:57:08
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:21:28

US3142013
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 21:57:08
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:21:28

US3142013
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 21:57:08
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:21:28

US3142013
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 21:57:08
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:21:28

US3142013
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 21:57:08
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'Jan 2010'	System	04 Aug 2020 01:21:28

FDA-CBER-2022-1614-0073774

US3142013
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 21:57:08
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '2010'	System	04 Aug 2020 01:21:28

FDA-CBER-2022-1614-0073775

US3142013
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 21:57:08
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:21:28

US3142013
Folder: Screening
Form: Medical History (8)
Generated On: 11 Aug 2021 21:57:08
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:21:28

FDA-CBER-2022-1614-0073777

US3142013
Folder: Screening
Form: Medical History (9)
Generated On: 11 Aug 2021 21:57:08
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:24:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:24:13
Data point term sent to Coder	System	04 Aug 2020 01:22:28
User entered 'Depression'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:21:46

FDA-CBER-2022-1614-0073778

US3142013
Folder: Screening
Form: Medical History (9)
Generated On: 11 Aug 2021 21:57:08
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'UN UNK 2006'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:21:46

US3142013
Folder: Screening
Form: Medical History (9)
Generated On: 11 Aug 2021 21:57:08
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:21:46

US3142013
Folder: Screening
Form: Medical History (9)
Generated On: 11 Aug 2021 21:57:08
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:21:46

US3142013
Folder: Screening
Form: Medical History (9)
Generated On: 11 Aug 2021 21:57:08
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:21:46

US3142013
Folder: Screening
Form: Medical History (9)
Generated On: 11 Aug 2021 21:57:08
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:21:46

US3142013
Folder: Screening
Form: Medical History (9)
Generated On: 11 Aug 2021 21:57:08
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'Jan 2006'	System	04 Aug 2020 01:21:46

US3142013
Folder: Screening
Form: Medical History (9)
Generated On: 11 Aug 2021 21:57:08
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '2006'	System	04 Aug 2020 01:21:46

FDA-CBER-2022-1614-0073785

US3142013
Folder: Screening
Form: Medical History (9)
Generated On: 11 Aug 2021 21:57:08
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:21:46

US3142013
Folder: Screening
Form: Medical History (9)
Generated On: 11 Aug 2021 21:57:08
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:21:46

FDA-CBER-2022-1614-0073787

US3142013
Folder: Screening
Form: Medical History (10)
Generated On: 11 Aug 2021 21:57:08
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:24:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:24:13
Data point term sent to Coder	System	04 Aug 2020 01:22:28
User entered 'Post-Traumatic Stress Disorder'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:22:09

US3142013
Folder: Screening
Form: Medical History (10)
Generated On: 11 Aug 2021 21:57:08
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'UN UNK 2019'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:22:09

US3142013
Folder: Screening
Form: Medical History (10)
Generated On: 11 Aug 2021 21:57:08
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:22:09

US3142013
Folder: Screening
Form: Medical History (10)
Generated On: 11 Aug 2021 21:57:08
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:22:09

US3142013
Folder: Screening
Form: Medical History (10)
Generated On: 11 Aug 2021 21:57:08
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:22:09

US3142013
Folder: Screening
Form: Medical History (10)
Generated On: 11 Aug 2021 21:57:08
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:22:09

US3142013
Folder: Screening
Form: Medical History (10)
Generated On: 11 Aug 2021 21:57:08
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'Jan 2019'	System	04 Aug 2020 01:22:09

FDA-CBER-2022-1614-0073794

US3142013
Folder: Screening
Form: Medical History (10)
Generated On: 11 Aug 2021 21:57:08
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '2019'	System	04 Aug 2020 01:22:09

FDA-CBER-2022-1614-0073795

US3142013
Folder: Screening
Form: Medical History (10)
Generated On: 11 Aug 2021 21:57:08
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:22:09

US3142013
Folder: Screening
Form: Medical History (10)
Generated On: 11 Aug 2021 21:57:08
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:22:09

FDA-CBER-2022-1614-0073797

US3142013
Folder: Screening
Form: Medical History (11)
Generated On: 11 Aug 2021 21:57:08
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Social issues NEC, PT: Substance use, LLT: Marijuana use - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 14:11:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 14:11:59
Data point term sent to Coder	System	04 Aug 2020 01:23:28
User entered 'Intermittent Marijuana User'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:22:52

US3142013
Folder: Screening
Form: Medical History (11)
Generated On: 11 Aug 2021 21:57:08
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'UN UNK 2015'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:22:52

US3142013
Folder: Screening
Form: Medical History (11)
Generated On: 11 Aug 2021 21:57:08
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:22:52

US3142013
Folder: Screening
Form: Medical History (11)
Generated On: 11 Aug 2021 21:57:08
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:22:52

US3142013
Folder: Screening
Form: Medical History (11)
Generated On: 11 Aug 2021 21:57:08
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:22:52

FDA-CBER-2022-1614-0073802

US3142013
Folder: Screening
Form: Medical History (11)
Generated On: 11 Aug 2021 21:57:08
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:22:52

US3142013
Folder: Screening
Form: Medical History (11)
Generated On: 11 Aug 2021 21:57:08
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'Jan 2015'	System	04 Aug 2020 01:22:52

US3142013
Folder: Screening
Form: Medical History (11)
Generated On: 11 Aug 2021 21:57:08
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '2015'	System	04 Aug 2020 01:22:52

FDA-CBER-2022-1614-0073805

US3142013
Folder: Screening
Form: Medical History (11)
Generated On: 11 Aug 2021 21:57:08
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:22:52

US3142013
Folder: Screening
Form: Medical History (11)
Generated On: 11 Aug 2021 21:57:08
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:22:52

FDA-CBER-2022-1614-0073807

US3142013
Folder: Screening
Form: Medical History (12)
Generated On: 11 Aug 2021 21:57:08
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:28:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:28:16
Data point term sent to Coder	System	04 Aug 2020 01:27:30
User entered 'Amoxicillin Allergy'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:26:42

US3142013
Folder: Screening
Form: Medical History (12)
Generated On: 11 Aug 2021 21:57:08
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'UN UNK 2015'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:26:42

FDA-CBER-2022-1614-0073809

US3142013
Folder: Screening
Form: Medical History (12)
Generated On: 11 Aug 2021 21:57:08
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:26:42

FDA-CBER-2022-1614-0073810

US3142013
Folder: Screening
Form: Medical History (12)
Generated On: 11 Aug 2021 21:57:08
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:26:42

US3142013
Folder: Screening
Form: Medical History (12)
Generated On: 11 Aug 2021 21:57:08
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:26:42

FDA-CBER-2022-1614-0073812

US3142013
Folder: Screening
Form: Medical History (12)
Generated On: 11 Aug 2021 21:57:08
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:26:42

US3142013
Folder: Screening
Form: Medical History (12)
Generated On: 11 Aug 2021 21:57:08
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'Jan 2015'	System	04 Aug 2020 01:26:42

US3142013
Folder: Screening
Form: Medical History (12)
Generated On: 11 Aug 2021 21:57:08
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '2015'	System	04 Aug 2020 01:26:42

FDA-CBER-2022-1614-0073815

US3142013
Folder: Screening
Form: Medical History (12)
Generated On: 11 Aug 2021 21:57:08
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:26:42

FDA-CBER-2022-1614-0073816

US3142013
Folder: Screening
Form: Medical History (12)
Generated On: 11 Aug 2021 21:57:08
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:26:42

FDA-CBER-2022-1614-0073817

US3142013
Folder: Screening
Form: Medical History (13)
Generated On: 11 Aug 2021 21:57:08
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:28:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:28:16
Data point term sent to Coder	System	04 Aug 2020 01:27:30
User entered 'Penicillin Allergy'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:27:04

US3142013
Folder: Screening
Form: Medical History (13)
Generated On: 11 Aug 2021 21:57:08
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Un UNK 2015'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:27:04

US3142013
Folder: Screening
Form: Medical History (13)
Generated On: 11 Aug 2021 21:57:08
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:27:04

US3142013
Folder: Screening
Form: Medical History (13)
Generated On: 11 Aug 2021 21:57:08
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:27:04

US3142013
Folder: Screening
Form: Medical History (13)
Generated On: 11 Aug 2021 21:57:08
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:27:04

US3142013
Folder: Screening
Form: Medical History (13)
Generated On: 11 Aug 2021 21:57:08
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:27:04

US3142013
Folder: Screening
Form: Medical History (13)
Generated On: 11 Aug 2021 21:57:08
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'Jan 2015'	System	04 Aug 2020 01:27:04

US3142013
Folder: Screening
Form: Medical History (13)
Generated On: 11 Aug 2021 21:57:08
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '2015'	System	04 Aug 2020 01:27:04

FDA-CBER-2022-1614-0073825

US3142013
Folder: Screening
Form: Medical History (13)
Generated On: 11 Aug 2021 21:57:08
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:27:04

FDA-CBER-2022-1614-0073826

US3142013
Folder: Screening
Form: Medical History (13)
Generated On: 11 Aug 2021 21:57:08
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:27:04

FDA-CBER-2022-1614-0073827

US3142013
Folder: Screening
Form: Medical History (14)
Generated On: 11 Aug 2021 21:57:08
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:54:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:54:14
Data point term sent to Coder	System	04 Aug 2020 01:53:37
User entered 'Anxiety'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:52:52

US3142013
Folder: Screening
Form: Medical History (14)
Generated On: 11 Aug 2021 21:57:08
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'UN UNK 2017'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:52:52

US3142013
Folder: Screening
Form: Medical History (14)
Generated On: 11 Aug 2021 21:57:08
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:52:52

US3142013
Folder: Screening
Form: Medical History (14)
Generated On: 11 Aug 2021 21:57:08
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:52:52

US3142013
Folder: Screening
Form: Medical History (14)
Generated On: 11 Aug 2021 21:57:08
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:52:52

US3142013
Folder: Screening
Form: Medical History (14)
Generated On: 11 Aug 2021 21:57:08
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:52:52

US3142013
Folder: Screening
Form: Medical History (14)
Generated On: 11 Aug 2021 21:57:08
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'Jan 2017'	System	04 Aug 2020 01:52:52

US3142013
Folder: Screening
Form: Medical History (14)
Generated On: 11 Aug 2021 21:57:08
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '2017'	System	04 Aug 2020 01:52:52

FDA-CBER-2022-1614-0073835

US3142013
Folder: Screening
Form: Medical History (14)
Generated On: 11 Aug 2021 21:57:08
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:52:52

US3142013
Folder: Screening
Form: Medical History (14)
Generated On: 11 Aug 2021 21:57:08
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:52:52

FDA-CBER-2022-1614-0073837

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:53:49

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '30 Jul 2020'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:53:49

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '13:37'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:53:49

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '30 Jul 2020 13:37'	System	04 Aug 2020 01:53:49

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '68' in	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:53:49
DataPoint set to visible.	System	30 Jul 2020 20:37:12

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '250.0' lb	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:53:49
DataPoint set to visible.	System	30 Jul 2020 20:37:12

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: User entered '38.09185'	System	16 Sep 2020 23:39:06
User entered '38.1'	System	04 Aug 2020 01:53:49
DataPoint set to visible.	System	30 Jul 2020 20:37:12

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'kg/m2'	System	04 Aug 2020 01:53:49
DataPoint set to visible.	System	30 Jul 2020 20:37:12

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
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.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 02:35:49
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.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:24:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:23:51
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.' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 13:54:47
User entered '98.4' F	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:53:49

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:23:51
User entered 'Other (Other)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:53:49

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:23:51
User entered 'Temporal'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:53:49

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:23:51
User entered '89'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:53:49

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'bpm'	System	04 Aug 2020 01:53:49

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:23:51
User entered '14'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:53:49

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'breaths/min'	System	04 Aug 2020 01:53:49

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:23:51
User entered '126'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:53:49

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'mmHg'	System	04 Aug 2020 01:53:49

FDA-CBER-2022-1614-0073854

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:23:51
User entered '77'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:53:49

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'mmHg'	System	04 Aug 2020 01:53:49

FDA-CBER-2022-1614-0073856

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0073857

US3142013
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0073858

US3142013
Folder: Screening
Form: Physical Examination
Generated On: 11 Aug 2021 21:57:08
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:54:06

US3142013
Folder: Screening
Form: Physical Examination
Generated On: 11 Aug 2021 21:57:08
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '30 Jul 2020'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:54:06

US3142013
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 21:57:08
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '30 Jul 2020'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:54:21

US3142013
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 21:57:08
Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:54:21

FDA-CBER-2022-1614-0073862

US3142013
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 21:57:08
If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:54:21

US3142013
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 21:57:08
If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:54:21

US3142013
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 21:57:08
If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:54:21

US3142013
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 21:57:08
Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:54:21

US3142013
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 21:57:08
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:54:21

US3142013
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 21:57:08
Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:54:21

US3142013
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:54:40

US3142013
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '30 Jul 2020'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:54:40

US3142013
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Urine (URINE)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:54:40

US3142013
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Negative (NEGATIVE)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:54:40

US3142013
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
Query 'Per CDM : Pregnancy test was performed however, Was FSH sample collected is No. Kindly review and reconcile or provide explanation.' canceled (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 20:42:48
User opened query 'Per CDM : Pregnancy test was performed however, Was FSH sample collected is No. Kindly review and reconcile or provide explanation.' (Site from DM).		19 Mar 2021 14:26:57
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:54:40

US3142013
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:54:40

US3142013
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:54:40

US3142013
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:54:40

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '1'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '0'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:57:08
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:01

US3142013
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:54:53

FDA-CBER-2022-1614-0073898

US3142013
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '30 Jul 2020'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:54:53

US3142013
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:54:53

US3142013
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'VISIT1'	System	04 Aug 2020 01:54:53

FDA-CBER-2022-1614-0073901

US3142013
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 21:57:08
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '30 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 20:39:07

FDA-CBER-2022-1614-0073902

US3142013
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 21:57:08
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:24:15
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:24:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Jul 2020 20:39:07
User entered '142409' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 20:39:07

US3142013
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 21:57:08
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 20:39:07

US3142013
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 21:57:08
Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:25

US3142013
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 21:57:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:25

FDA-CBER-2022-1614-0073906

US3142013
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 21:57:08
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:25

FDA-CBER-2022-1614-0073907

US3142013
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 21:57:08
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:25

FDA-CBER-2022-1614-0073908

US3142013
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 21:57:08
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	30 Jul 2020 20:38:25

FDA-CBER-2022-1614-0073909

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:57:08
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
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 15:22:29
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 16:23:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:23:10
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 06:22:52
User entered '68' in	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073910

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:57:08
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:23:10
User entered '250.0' lb	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:57:08
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
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 15:22:29
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 16:23:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:23:10
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 06:22:52
User entered '68' in	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:57:08
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:23:10
User entered '250.0' lb	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Pre-Dose (PREDOSE)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '30 Jul 2020'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073916

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '13:37'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073917

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '30 Jul 2020 13:37'	System	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073918

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '98.4' F	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Other (Other)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Temporal'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073921

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '89'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073922

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'bpm'	System	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073923

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '14'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'breaths/min'	System	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073925

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '126'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073926

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'mmHg'	System	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073927

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '77'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073928

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'mmHg'	System	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073929

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:57:08
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
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 15:22:29
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 16:23:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:23:10
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 06:22:52
User entered '68' in	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073930

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:57:08
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:23:10
User entered '250.0' lb	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Post-Dose (POSTDOSE)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073933

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '30 Jul 2020'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073934

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User closed 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).	(b) (4), (b) (6)	06 Aug 2020 12:04:42
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 minute observation per protocol' (Site from System).	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:49
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	04 Aug 2020 01:56:29
User entered '15:20'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '30 Jul 2020 15:20'	System	04 Aug 2020 01:56:29

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '99.1' F	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073937

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Other (Other)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Temporal'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '80'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'bpm'	System	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073941

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '12'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'breaths/min'	System	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073943

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '120'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073944

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'mmHg'	System	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073945

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '84'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:29

US3142013
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'mmHg'	System	04 Aug 2020 01:56:29

FDA-CBER-2022-1614-0073947

US3142013
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 11 Aug 2021 21:57:08
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:59

US3142013
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 11 Aug 2021 21:57:08
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '30 Jul 2020'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:56:59

FDA-CBER-2022-1614-0073949

US3142013
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User closed query 'Per CDM: Per CCGs, If Screening and Visit 1 Day 1 are done on the same day, please enter Pregnancy Test at Screening and Select No at Visit 1 Day 1 for Pregnancy Test. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 17:55:27
Query 'Per CDM: Per CCGs, If Screening and Visit 1 Day 1 are done on the same day, please enter Pregnancy Test at Screening and Select No at Visit 1 Day 1 for Pregnancy Test. Thank you.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	10 Nov 2020 21:24:07
User entered 'No (N)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	10 Nov 2020 21:23:58
User opened query 'Per CDM: Per CCGs, If Screening and Visit 1 Day 1 are done on the same day, please enter Pregnancy Test at Screening and Select No at Visit 1 Day 1 for Pregnancy Test. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:13:45
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:57:15

US3142013
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	10 Nov 2020 21:23:58
User entered '30 Jul 2020'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:57:15

US3142013
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	10 Nov 2020 21:23:58
User entered 'Urine (URINE)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:57:15

US3142013
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	10 Nov 2020 21:23:58
User entered 'Negative (NEGATIVE)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:57:15

US3142013
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User closed query 'Per CDM: Screening and V1D1 have occurred on the same day. Please consider to mark response for Was FSH sample collected? as No' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 03:28:09
Query 'Per CDM: Screening and V1D1 have occurred on the same day. Please consider to mark response for Was FSH sample collected? as No' answered with 'now complete ' (Site from DM).	Meghan York (b) (4) (b) (4)	19 Nov 2020 18:34:24
User entered 'No (N)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	19 Nov 2020 18:34:15
User opened query 'Per CDM: Screening and V1D1 have occurred on the same day. Please consider to mark response for Was FSH sample collected? as No' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 13:18:42
User entered empty; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	10 Nov 2020 21:23:58
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:57:15

US3142013
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:57:15

US3142013
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:57:15

US3142013
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:57:15

US3142013
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:57:08
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Jul 2020 17:44:32

US3142013
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:57:08
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	(b) (4), (b) (6)	31 Jul 2020 17:44:32

US3142013
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:57:08
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	(b) (4), (b) (6)	31 Jul 2020 17:44:32

US3142013
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:57:08
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'MRNA-1273 OR PLACEBO'	System	31 Jul 2020 17:44:32

US3142013
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:57:08
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '30 Jul 2020'	(b) (4), (b) (6)	31 Jul 2020 17:44:32

US3142013
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:57:08
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '14:50'	(b) (4), (b) (6)	31 Jul 2020 17:44:32

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US3142013
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:57:08
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '30 Jul 2020 14:50'	System	31 Jul 2020 17:44:32

US3142013
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:57:08
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:55:14
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 17:44:32

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US3142013
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:57:08
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'ONCE'	System	31 Jul 2020 17:44:32

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US3142013
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:57:08
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'INTRAMUSCULAR'	System	31 Jul 2020 17:44:32

US3142013
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:57:08
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:57:39

US3142013
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:57:08
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '30 Jul 2020'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:57:39

US3142013
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:57:08
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '14:19'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:57:39

US3142013
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:57:08
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '30 Jul 2020 14:19'	System	04 Aug 2020 01:57:39

US3142013
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 11 Aug 2021 21:57:08
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '30 Jul 2020'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:57:57

US3142013
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 21:57:08
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:57:57

US3142013
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 21:57:08
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:57:57

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US3142013
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 21:57:08
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '14:19'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:57:57

US3142013
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 21:57:08
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '30 Jul 2020 14:19'	System	04 Aug 2020 01:57:57

FDA-CBER-2022-1614-0073976

US3142013
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 21:57:08
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:57:57

US3142013
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 21:57:08
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:57:57

FDA-CBER-2022-1614-0073978

US3142013
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 21:57:08
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '14:19'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:57:57

FDA-CBER-2022-1614-0073979

US3142013
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 21:57:08
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '30 Jul 2020 14:19'	System	04 Aug 2020 01:57:57

US3142013
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:58:04

US3142013
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1'	System	04 Aug 2020 01:58:04

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US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0073984

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0073985

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0073986

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0073987

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0073988

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0073989

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '30 Jul 2020 15:10'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0073990

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '30 Jul 2020 17:40'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0073991

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0073993

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0073994

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0073995

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0073996

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0073998

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '30 Jul 2020 18:35'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0073999

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '31 Jul 2020 11:59'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 2'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:57:08
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T09:43:20', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '0ccff280-e3e4-443d-944c-60461156b50a'	System	01 Aug 2020 15:43:45
User entered 'Yes (Y)'	System	01 Aug 2020 15:43:45

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:57:08
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T09:43:37', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '0ccff280-e3e4-443d-944c-60461156b50a'	System	01 Aug 2020 15:43:45
User entered '98.4'	System	01 Aug 2020 15:43:45

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:57:08
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T09:43:40', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '0ccff280-e3e4-443d-944c-60461156b50a'	System	01 Aug 2020 15:43:45
User entered 'No (N)'	System	01 Aug 2020 15:43:45

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T09:43:43', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '0ccff280-e3e4-443d-944c-60461156b50a'	System	01 Aug 2020 15:43:45
User entered '01 Aug 2020 09:43'	System	01 Aug 2020 15:43:45

FDA-CBER-2022-1614-0074005

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '31 Jul 2020 12:00'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074006

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074007

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 3'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:57:08
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T12:00:51', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '78030305-8847-4021-b65b-43d53c6eff2b'	System	01 Aug 2020 18:01:06
User entered 'Yes (Y)'	System	01 Aug 2020 18:01:06

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:57:08
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T12:00:56', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '78030305-8847-4021-b65b-43d53c6eff2b'	System	01 Aug 2020 18:01:06
User entered '98.6'	System	01 Aug 2020 18:01:06

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:57:08
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T12:00:59', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '78030305-8847-4021-b65b-43d53c6eff2b'	System	01 Aug 2020 18:01:06
User entered 'No (N)'	System	01 Aug 2020 18:01:06

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T12:01:02', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '78030305-8847-4021-b65b-43d53c6eff2b'	System	01 Aug 2020 18:01:06
User entered '01 Aug 2020 12:01'	System	01 Aug 2020 18:01:06

FDA-CBER-2022-1614-0074012

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074013

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074014

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 4'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:57:08
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-02T21:29:02', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '66006e26-cd47-45c5-b6f3-74d9dd25a55f'	System	03 Aug 2020 03:29:34
User entered 'Yes (Y)'	System	03 Aug 2020 03:29:34

FDA-CBER-2022-1614-0074016

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:57:08
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-02T21:29:23', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '66006e26-cd47-45c5-b6f3-74d9dd25a55f'	System	03 Aug 2020 03:29:34
User entered '98.4'	System	03 Aug 2020 03:29:34

FDA-CBER-2022-1614-0074017

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:57:08
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-02T21:29:27', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '66006e26-cd47-45c5-b6f3-74d9dd25a55f'	System	03 Aug 2020 03:29:34
User entered 'No (N)'	System	03 Aug 2020 03:29:34

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-02T21:29:30', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '66006e26-cd47-45c5-b6f3-74d9dd25a55f'	System	03 Aug 2020 03:29:34
User entered '02 Aug 2020 21:29'	System	03 Aug 2020 03:29:34

FDA-CBER-2022-1614-0074019

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074020

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074021

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 5'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074022

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:57:08
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074023

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:57:08
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074024

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:57:08
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:57:08
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074026

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:57:08
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074027

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074028

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074029

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074030

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 6'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:57:08
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-04T12:18:04', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'ad37036f-39bd-4c32-88f5-bc42b46a55e7'	System	04 Aug 2020 18:18:22
User entered 'Yes (Y)'	System	04 Aug 2020 18:18:22

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:57:08
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-04T12:18:09', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'ad37036f-39bd-4c32-88f5-bc42b46a55e7'	System	04 Aug 2020 18:18:22
User entered '98.7'	System	04 Aug 2020 18:18:22

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:57:08
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-04T12:18:11', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'ad37036f-39bd-4c32-88f5-bc42b46a55e7'	System	04 Aug 2020 18:18:22
User entered 'No (N)'	System	04 Aug 2020 18:18:22

FDA-CBER-2022-1614-0074034

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-04T12:18:18', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'ad37036f-39bd-4c32-88f5-bc42b46a55e7'	System	04 Aug 2020 18:18:22
User entered '04 Aug 2020 12:18'	System	04 Aug 2020 18:18:22

FDA-CBER-2022-1614-0074035

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074036

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074037

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 7'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:57:08
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-05T13:00:53', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '7d9f6e5e-a8f2-4ed9-a279-4316e8be889d'	System	05 Aug 2020 19:01:06
User entered 'Yes (Y)'	System	05 Aug 2020 19:01:06

FDA-CBER-2022-1614-0074039

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:57:08
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-05T13:00:59', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '7d9f6e5e-a8f2-4ed9-a279-4316e8be889d'	System	05 Aug 2020 19:01:06
User entered '98.5'	System	05 Aug 2020 19:01:06

FDA-CBER-2022-1614-0074040

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:57:08
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-05T13:01:02', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '7d9f6e5e-a8f2-4ed9-a279-4316e8be889d'	System	05 Aug 2020 19:01:06
User entered 'No (N)'	System	05 Aug 2020 19:01:06

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-05T13:01:04', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '7d9f6e5e-a8f2-4ed9-a279-4316e8be889d'	System	05 Aug 2020 19:01:06
User entered '05 Aug 2020 13:01'	System	05 Aug 2020 19:01:06

FDA-CBER-2022-1614-0074042

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074043

US3142013
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074044

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

FDA-CBER-2022-1614-0074046

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074047

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

FDA-CBER-2022-1614-0074048

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074049

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

FDA-CBER-2022-1614-0074050

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

FDA-CBER-2022-1614-0074051

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074052

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '30 Jul 2020 15:10'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '30 Jul 2020 17:40'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074054

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

FDA-CBER-2022-1614-0074056

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074057

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

FDA-CBER-2022-1614-0074058

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074059

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

FDA-CBER-2022-1614-0074060

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

FDA-CBER-2022-1614-0074061

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074062

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '30 Jul 2020 18:35'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074063

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '31 Jul 2020 11:59'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 2'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T09:42:25', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'bd1bf69e-29ac-4476-a620-28f64858f721'	System	01 Aug 2020 15:42:47
User entered 'None (1)'	System	01 Aug 2020 15:42:47

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:57:08
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T09:42:28', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'bd1bf69e-29ac-4476-a620-28f64858f721'	System	01 Aug 2020 15:42:47
User entered 'No (N)'	System	01 Aug 2020 15:42:47

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:57:08
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T09:42:32', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'bd1bf69e-29ac-4476-a620-28f64858f721'	System	01 Aug 2020 15:42:47
User entered 'No (N)'	System	01 Aug 2020 15:42:47

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T09:42:40', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'bd1bf69e-29ac-4476-a620-28f64858f721'	System	01 Aug 2020 15:42:47
User entered 'None (1)'	System	01 Aug 2020 15:42:47

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T09:42:44', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'bd1bf69e-29ac-4476-a620-28f64858f721'	System	01 Aug 2020 15:42:47
User entered '01 Aug 2020 09:42'	System	01 Aug 2020 15:42:47

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US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '31 Jul 2020 12:00'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074071

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074072

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 3'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T12:01:08', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '1c766d30-a369-490f-a6e0-3c88552c5ccc'	System	01 Aug 2020 18:01:19
User entered 'None (1)'	System	01 Aug 2020 18:01:19

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:57:08
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T12:01:11', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '1c766d30-a369-490f-a6e0-3c88552c5ccc'	System	01 Aug 2020 18:01:19
User entered 'No (N)'	System	01 Aug 2020 18:01:19

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:57:08
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T12:01:13', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '1c766d30-a369-490f-a6e0-3c88552c5ccc'	System	01 Aug 2020 18:01:19
User entered 'No (N)'	System	01 Aug 2020 18:01:19

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T12:01:15', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '1c766d30-a369-490f-a6e0-3c88552c5ccc'	System	01 Aug 2020 18:01:19
User entered 'None (1)'	System	01 Aug 2020 18:01:19

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US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T12:01:18', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '1c766d30-a369-490f-a6e0-3c88552c5ccc'	System	01 Aug 2020 18:01:19
User entered '01 Aug 2020 12:01'	System	01 Aug 2020 18:01:19

FDA-CBER-2022-1614-0074078

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 4'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-02T12:11:14', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '7a0995d2-2230-4166-821d-52fe27af4008'	System	02 Aug 2020 18:11:25
User entered 'None (1)'	System	02 Aug 2020 18:11:25

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:57:08
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-02T12:11:16', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '7a0995d2-2230-4166-821d-52fe27af4008'	System	02 Aug 2020 18:11:25
User entered 'No (N)'	System	02 Aug 2020 18:11:25

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:57:08
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-02T12:11:18', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '7a0995d2-2230-4166-821d-52fe27af4008'	System	02 Aug 2020 18:11:25
User entered 'No (N)'	System	02 Aug 2020 18:11:25

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-02T12:11:21', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '7a0995d2-2230-4166-821d-52fe27af4008'	System	02 Aug 2020 18:11:25
User entered 'None (1)'	System	02 Aug 2020 18:11:25

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-02T12:11:23', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '7a0995d2-2230-4166-821d-52fe27af4008'	System	02 Aug 2020 18:11:25
User entered '02 Aug 2020 12:11'	System	02 Aug 2020 18:11:25

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 17:44:32

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US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 17:44:32

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US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 5'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

FDA-CBER-2022-1614-0074090

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:57:08
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:57:08
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

FDA-CBER-2022-1614-0074094

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

FDA-CBER-2022-1614-0074095

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074096

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074098

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 6'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-04T12:18:23', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'e5758fc7-36c1-4a7c-8054-e7e96adb2dcd'	System	04 Aug 2020 18:18:33
User entered 'None (1)'	System	04 Aug 2020 18:18:33

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:57:08
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-04T12:18:24', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'e5758fc7-36c1-4a7c-8054-e7e96adb2dcd'	System	04 Aug 2020 18:18:33
User entered 'No (N)'	System	04 Aug 2020 18:18:33

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:57:08
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-04T12:18:26', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'e5758fc7-36c1-4a7c-8054-e7e96adb2dcd'	System	04 Aug 2020 18:18:33
User entered 'No (N)'	System	04 Aug 2020 18:18:33

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-04T12:18:28', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'e5758fc7-36c1-4a7c-8054-e7e96adb2dcd'	System	04 Aug 2020 18:18:33
User entered 'None (1)'	System	04 Aug 2020 18:18:33

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-04T12:18:29', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'e5758fc7-36c1-4a7c-8054-e7e96adb2dcd'	System	04 Aug 2020 18:18:33
User entered '04 Aug 2020 12:18'	System	04 Aug 2020 18:18:33

FDA-CBER-2022-1614-0074104

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074105

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074106

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 7'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-05T13:00:41', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'c88b6e79-5a05-463c-9310-f5ec8e6ec86a'	System	05 Aug 2020 19:00:50
User entered 'None (1)'	System	05 Aug 2020 19:00:50

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:57:08
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-05T13:00:43', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'c88b6e79-5a05-463c-9310-f5ec8e6ec86a'	System	05 Aug 2020 19:00:50
User entered 'No (N)'	System	05 Aug 2020 19:00:50

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:57:08
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-05T13:00:44', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'c88b6e79-5a05-463c-9310-f5ec8e6ec86a'	System	05 Aug 2020 19:00:50
User entered 'No (N)'	System	05 Aug 2020 19:00:50

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-05T13:00:46', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'c88b6e79-5a05-463c-9310-f5ec8e6ec86a'	System	05 Aug 2020 19:00:50
User entered 'None (1)'	System	05 Aug 2020 19:00:50

FDA-CBER-2022-1614-0074111

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-05T13:00:48', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'c88b6e79-5a05-463c-9310-f5ec8e6ec86a'	System	05 Aug 2020 19:00:50
User entered '05 Aug 2020 13:00'	System	05 Aug 2020 19:00:50

FDA-CBER-2022-1614-0074112

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074113

US3142013
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074114

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074116

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074117

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074118

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074120

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074121

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074123

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '30 Jul 2020 15:10'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074124

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '30 Jul 2020 17:40'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074125

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074127

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074128

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074129

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074131

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074132

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

FDA-CBER-2022-1614-0074133

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074134

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '30 Jul 2020 18:35'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074135

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '31 Jul 2020 11:59'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074136

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 2'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T09:41:31', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '4dc1b692-bb45-4253-bed2-1fb1a6e4bec1'	System	01 Aug 2020 15:42:23
User entered 'None (0)'	System	01 Aug 2020 15:42:23

FDA-CBER-2022-1614-0074138

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T09:41:44', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '4dc1b692-bb45-4253-bed2-1fb1a6e4bec1'	System	01 Aug 2020 15:42:23
User entered 'No interference with activity (1)'	System	01 Aug 2020 15:42:23

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T09:41:48', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '4dc1b692-bb45-4253-bed2-1fb1a6e4bec1'	System	01 Aug 2020 15:42:23
User entered 'None (0)'	System	01 Aug 2020 15:42:23

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T09:41:55', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '4dc1b692-bb45-4253-bed2-1fb1a6e4bec1'	System	01 Aug 2020 15:42:23
User entered 'None (0)'	System	01 Aug 2020 15:42:23

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T09:41:58', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '4dc1b692-bb45-4253-bed2-1fb1a6e4bec1'	System	01 Aug 2020 15:42:23
User entered 'None (0)'	System	01 Aug 2020 15:42:23

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T09:42:00', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '4dc1b692-bb45-4253-bed2-1fb1a6e4bec1'	System	01 Aug 2020 15:42:23
User entered 'None (0)'	System	01 Aug 2020 15:42:23

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T09:42:12', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '4dc1b692-bb45-4253-bed2-1fb1a6e4bec1'	System	01 Aug 2020 15:42:23
User entered 'No (N)'	System	01 Aug 2020 15:42:23

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T09:42:19', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '4dc1b692-bb45-4253-bed2-1fb1a6e4bec1'	System	01 Aug 2020 15:42:23
User entered '01 Aug 2020 09:42'	System	01 Aug 2020 15:42:23

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '31 Jul 2020 12:00'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074146

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074147

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 3'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T12:01:22', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'f507f63b-468d-48c8-be12-3d46c88ec72a'	System	01 Aug 2020 18:01:40
User entered 'None (0)'	System	01 Aug 2020 18:01:40

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T12:01:25', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'f507f63b-468d-48c8-be12-3d46c88ec72a'	System	01 Aug 2020 18:01:40
User entered 'No interference with activity (1)'	System	01 Aug 2020 18:01:40

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T12:01:27', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'f507f63b-468d-48c8-be12-3d46c88ec72a'	System	01 Aug 2020 18:01:40
User entered 'None (0)'	System	01 Aug 2020 18:01:40

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T12:01:31', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'f507f63b-468d-48c8-be12-3d46c88ec72a'	System	01 Aug 2020 18:01:40
User entered 'None (0)'	System	01 Aug 2020 18:01:40

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T12:01:32', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'f507f63b-468d-48c8-be12-3d46c88ec72a'	System	01 Aug 2020 18:01:40
User entered 'None (0)'	System	01 Aug 2020 18:01:40

FDA-CBER-2022-1614-0074153

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T12:01:34', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'f507f63b-468d-48c8-be12-3d46c88ec72a'	System	01 Aug 2020 18:01:40
User entered 'None (0)'	System	01 Aug 2020 18:01:40

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T12:01:37', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'f507f63b-468d-48c8-be12-3d46c88ec72a'	System	01 Aug 2020 18:01:40
User entered 'No (N)'	System	01 Aug 2020 18:01:40

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-01T12:01:39', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'f507f63b-468d-48c8-be12-3d46c88ec72a'	System	01 Aug 2020 18:01:40
User entered '01 Aug 2020 12:01'	System	01 Aug 2020 18:01:40

FDA-CBER-2022-1614-0074156

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074157

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074158

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 4'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-02T12:10:35', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'b8ada012-56e3-4055-b233-f6f2fa3d7695'	System	02 Aug 2020 18:11:10
User entered 'No interference with activity (1)'	System	02 Aug 2020 18:11:10

FDA-CBER-2022-1614-0074160

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-02T12:10:40', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'b8ada012-56e3-4055-b233-f6f2fa3d7695'	System	02 Aug 2020 18:11:10
User entered 'Some interference with activity (2)'	System	02 Aug 2020 18:11:10

FDA-CBER-2022-1614-0074161

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-02T12:10:42', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'b8ada012-56e3-4055-b233-f6f2fa3d7695'	System	02 Aug 2020 18:11:10
User entered 'None (0)'	System	02 Aug 2020 18:11:10

FDA-CBER-2022-1614-0074162

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-02T12:10:55', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'b8ada012-56e3-4055-b233-f6f2fa3d7695'	System	02 Aug 2020 18:11:10
User entered 'Some interference with activity (2)'	System	02 Aug 2020 18:11:10

FDA-CBER-2022-1614-0074163

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-02T12:10:58', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'b8ada012-56e3-4055-b233-f6f2fa3d7695'	System	02 Aug 2020 18:11:10
User entered 'None (0)'	System	02 Aug 2020 18:11:10

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-02T12:11:02', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'b8ada012-56e3-4055-b233-f6f2fa3d7695'	System	02 Aug 2020 18:11:10
User entered 'No interference with activity (1)'	System	02 Aug 2020 18:11:10

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-02T12:11:05', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'b8ada012-56e3-4055-b233-f6f2fa3d7695'	System	02 Aug 2020 18:11:10
User entered 'No (N)'	System	02 Aug 2020 18:11:10

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-02T12:11:08', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'b8ada012-56e3-4055-b233-f6f2fa3d7695'	System	02 Aug 2020 18:11:10
User entered '02 Aug 2020 12:11'	System	02 Aug 2020 18:11:10

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074168

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 5'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074171

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074172

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074173

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074174

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074175

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074176

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074178

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074179

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 6'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-04T12:17:42', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '1581ba2d-f2a9-4e82-9721-ab29aa071f0c'	System	04 Aug 2020 18:18:03
User entered 'None (0)'	System	04 Aug 2020 18:18:03

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-04T12:17:44', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '1581ba2d-f2a9-4e82-9721-ab29aa071f0c'	System	04 Aug 2020 18:18:03
User entered 'No interference with activity (1)'	System	04 Aug 2020 18:18:03

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-04T12:17:47', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '1581ba2d-f2a9-4e82-9721-ab29aa071f0c'	System	04 Aug 2020 18:18:03
User entered 'No interference with activity (1)'	System	04 Aug 2020 18:18:03

FDA-CBER-2022-1614-0074184

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-04T12:17:49', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '1581ba2d-f2a9-4e82-9721-ab29aa071f0c'	System	04 Aug 2020 18:18:03
User entered 'No interference with activity (1)'	System	04 Aug 2020 18:18:03

FDA-CBER-2022-1614-0074185

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-04T12:17:51', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '1581ba2d-f2a9-4e82-9721-ab29aa071f0c'	System	04 Aug 2020 18:18:03
User entered 'None (0)'	System	04 Aug 2020 18:18:03

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-04T12:17:54', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '1581ba2d-f2a9-4e82-9721-ab29aa071f0c'	System	04 Aug 2020 18:18:03
User entered 'None (0)'	System	04 Aug 2020 18:18:03

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-04T12:17:56', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '1581ba2d-f2a9-4e82-9721-ab29aa071f0c'	System	04 Aug 2020 18:18:03
User entered 'No (N)'	System	04 Aug 2020 18:18:03

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-04T12:17:58', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '1581ba2d-f2a9-4e82-9721-ab29aa071f0c'	System	04 Aug 2020 18:18:03
User entered '04 Aug 2020 12:17'	System	04 Aug 2020 18:18:03

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 17:44:32

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US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 7'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-05T13:00:21', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '4a21f166-252a-4df5-871a-a57992e93d37'	System	05 Aug 2020 19:00:40
User entered 'No interference with activity (1)'	System	05 Aug 2020 19:00:40

FDA-CBER-2022-1614-0074193

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-05T13:00:24', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '4a21f166-252a-4df5-871a-a57992e93d37'	System	05 Aug 2020 19:00:40
User entered 'No interference with activity (1)'	System	05 Aug 2020 19:00:40

FDA-CBER-2022-1614-0074194

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-05T13:00:27', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '4a21f166-252a-4df5-871a-a57992e93d37'	System	05 Aug 2020 19:00:40
User entered 'None (0)'	System	05 Aug 2020 19:00:40

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-05T13:00:29', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '4a21f166-252a-4df5-871a-a57992e93d37'	System	05 Aug 2020 19:00:40
User entered 'None (0)'	System	05 Aug 2020 19:00:40

FDA-CBER-2022-1614-0074196

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-05T13:00:31', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '4a21f166-252a-4df5-871a-a57992e93d37'	System	05 Aug 2020 19:00:40
User entered 'None (0)'	System	05 Aug 2020 19:00:40

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-05T13:00:32', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '4a21f166-252a-4df5-871a-a57992e93d37'	System	05 Aug 2020 19:00:40
User entered 'None (0)'	System	05 Aug 2020 19:00:40

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-05T13:00:36', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '4a21f166-252a-4df5-871a-a57992e93d37'	System	05 Aug 2020 19:00:40
User entered 'No (N)'	System	05 Aug 2020 19:00:40

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-05T13:00:38', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '4a21f166-252a-4df5-871a-a57992e93d37'	System	05 Aug 2020 19:00:40
User entered '05 Aug 2020 13:00'	System	05 Aug 2020 19:00:40

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074201

US3142013
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 17:44:32

US3142013
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	05 Aug 2020 19:00:40
User entered 'Day 8'	System	05 Aug 2020 19:00:40

US3142013
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 11 Aug 2021 21:57:08
Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-07T09:35:27', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '8d4897eb-fa29-4981-82d5-c89a70b2939a'	System	07 Aug 2020 15:35:31
User entered 'No interference with activity (1)'	System	07 Aug 2020 15:35:31

US3142013
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-07T09:35:29', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '8d4897eb-fa29-4981-82d5-c89a70b2939a'	System	07 Aug 2020 15:35:31
User entered '07 Aug 2020 09:35'	System	07 Aug 2020 15:35:31

FDA-CBER-2022-1614-0074205

US3142013
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 19:00:40

FDA-CBER-2022-1614-0074206

US3142013
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 19:00:40

US3142013
Folder: Diary Dose 1 (1)
Form: Headache_Day(9)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	05 Aug 2020 19:00:40
User entered 'Day 9'	System	05 Aug 2020 19:00:40

US3142013
Folder: Diary Dose 1 (1)
Form: Headache_Day(9)
Generated On: 11 Aug 2021 21:57:08
Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-07T12:00:10', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '842d8419-acb7-4305-86a3-57e64c104b41'	System	07 Aug 2020 18:00:14
User entered 'No interference with activity (1)'	System	07 Aug 2020 18:00:14

FDA-CBER-2022-1614-0074209

US3142013
Folder: Diary Dose 1 (1)
Form: Headache_Day(9)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-07T12:00:12', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '842d8419-acb7-4305-86a3-57e64c104b41'	System	07 Aug 2020 18:00:14
User entered '07 Aug 2020 12:00'	System	07 Aug 2020 18:00:14

US3142013
Folder: Diary Dose 1 (1)
Form: Headache_Day(9)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 19:00:40

FDA-CBER-2022-1614-0074211

US3142013
Folder: Diary Dose 1 (1)
Form: Headache_Day(9)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 19:00:40

FDA-CBER-2022-1614-0074212

US3142013
Folder: Diary Dose 1 (1)
Form: Headache_Day(10)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	07 Aug 2020 15:35:31
User entered 'Day 10'	System	07 Aug 2020 15:35:31

US3142013
Folder: Diary Dose 1 (1)
Form: Headache_Day(10)
Generated On: 11 Aug 2021 21:57:08
Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-08T12:02:31', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '365c78f0-e099-4df2-9814-465982730282'	System	08 Aug 2020 18:02:37
User entered 'None (0)'	System	08 Aug 2020 18:02:37

FDA-CBER-2022-1614-0074214

US3142013
Folder: Diary Dose 1 (1)
Form: Headache_Day(10)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-08T12:02:33', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '365c78f0-e099-4df2-9814-465982730282'	System	08 Aug 2020 18:02:37
User entered '08 Aug 2020 12:02'	System	08 Aug 2020 18:02:37

US3142013
Folder: Diary Dose 1 (1)
Form: Headache_Day(10)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 15:35:31

FDA-CBER-2022-1614-0074216

US3142013
Folder: Diary Dose 1 (1)
Form: Headache_Day(10)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 15:35:31

FDA-CBER-2022-1614-0074217

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	04 Aug 2020 18:18:03
User entered 'Day 8'	System	04 Aug 2020 18:18:03

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 11 Aug 2021 21:57:08
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-07T09:35:20', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '3dc34a8b-8609-4265-a563-3403024c95d0'	System	07 Aug 2020 15:35:24
User entered 'No interference with activity (1)'	System	07 Aug 2020 15:35:24

FDA-CBER-2022-1614-0074219

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-07T09:35:22', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '3dc34a8b-8609-4265-a563-3403024c95d0'	System	07 Aug 2020 15:35:24
User entered '07 Aug 2020 09:35'	System	07 Aug 2020 15:35:24

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 18:18:03

FDA-CBER-2022-1614-0074221

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 18:18:03

FDA-CBER-2022-1614-0074222

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	05 Aug 2020 19:00:40
User entered 'Day 9'	System	05 Aug 2020 19:00:40

FDA-CBER-2022-1614-0074223

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 11 Aug 2021 21:57:08
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-07T12:00:17', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '723f4e7c-6b5b-434d-981c-b35378165b55'	System	07 Aug 2020 18:00:24
User entered 'No interference with activity (1)'	System	07 Aug 2020 18:00:24

FDA-CBER-2022-1614-0074224

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-07T12:00:19', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '723f4e7c-6b5b-434d-981c-b35378165b55'	System	07 Aug 2020 18:00:24
User entered '07 Aug 2020 12:00'	System	07 Aug 2020 18:00:24

FDA-CBER-2022-1614-0074225

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 19:00:40

FDA-CBER-2022-1614-0074226

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 19:00:40

FDA-CBER-2022-1614-0074227

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(10)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	07 Aug 2020 15:35:24
User entered 'Day 10'	System	07 Aug 2020 15:35:24

FDA-CBER-2022-1614-0074228

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(10)
Generated On: 11 Aug 2021 21:57:08
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-08T12:02:36', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '94ad332f-7ecc-4e8b-bf4b-7518f949aef9'	System	08 Aug 2020 18:02:40
User entered 'No interference with activity (1)'	System	08 Aug 2020 18:02:40

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(10)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-08T12:02:37', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '94ad332f-7ecc-4e8b-bf4b-7518f949aef9'	System	08 Aug 2020 18:02:40
User entered '08 Aug 2020 12:02'	System	08 Aug 2020 18:02:40

FDA-CBER-2022-1614-0074230

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(10)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 15:35:24

FDA-CBER-2022-1614-0074231

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(10)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 15:35:24

FDA-CBER-2022-1614-0074232

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(11)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	07 Aug 2020 18:00:24
User entered 'Day 11'	System	07 Aug 2020 18:00:24

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(11)
Generated On: 11 Aug 2021 21:57:08
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-09T17:32:33', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'de3570f2-58eb-48f0-9c41-f490746cb721'	System	09 Aug 2020 23:32:39
User entered 'None (0)'	System	09 Aug 2020 23:32:39

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(11)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-09T17:32:37', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'de3570f2-58eb-48f0-9c41-f490746cb721'	System	09 Aug 2020 23:32:39
User entered '09 Aug 2020 17:32'	System	09 Aug 2020 23:32:39

FDA-CBER-2022-1614-0074235

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(11)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 18:00:24

FDA-CBER-2022-1614-0074236

US3142013
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(11)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 18:00:24

FDA-CBER-2022-1614-0074237

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	04 Aug 2020 18:18:03
User entered 'Day 8'	System	04 Aug 2020 18:18:03

FDA-CBER-2022-1614-0074238

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-07T09:35:14', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '75ad3ba0-a986-4d27-8d9c-a4801c50daba'	System	07 Aug 2020 15:35:20
User entered 'No (N)'	System	07 Aug 2020 15:35:20

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 11 Aug 2021 21:57:08
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-07T09:35:16', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '75ad3ba0-a986-4d27-8d9c-a4801c50daba'	System	07 Aug 2020 15:35:20
User entered '07 Aug 2020 09:35'	System	07 Aug 2020 15:35:20

FDA-CBER-2022-1614-0074240

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 18:18:03

FDA-CBER-2022-1614-0074241

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 18:18:03

FDA-CBER-2022-1614-0074242

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	05 Aug 2020 19:00:40
User entered 'Day 9'	System	05 Aug 2020 19:00:40

FDA-CBER-2022-1614-0074243

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-07T12:00:24', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '2c63151f-e680-469f-8b59-5fc7eb98974e'	System	07 Aug 2020 18:00:30
User entered 'No (N)'	System	07 Aug 2020 18:00:30

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 11 Aug 2021 21:57:08
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-07T12:00:26', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '2c63151f-e680-469f-8b59-5fc7eb98974e'	System	07 Aug 2020 18:00:30
User entered '07 Aug 2020 12:00'	System	07 Aug 2020 18:00:30

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 19:00:40

FDA-CBER-2022-1614-0074246

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 19:00:40

FDA-CBER-2022-1614-0074247

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	07 Aug 2020 15:35:24
User entered 'Day 10'	System	07 Aug 2020 15:35:24

FDA-CBER-2022-1614-0074248

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-08T12:02:41', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'b0da5fd8-db29-4ccf-a766-682a921bf9f2'	System	08 Aug 2020 18:02:43
User entered 'No (N)'	System	08 Aug 2020 18:02:43

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 11 Aug 2021 21:57:08
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-08T12:02:42', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'b0da5fd8-db29-4ccf-a766-682a921bf9f2'	System	08 Aug 2020 18:02:43
User entered '08 Aug 2020 12:02'	System	08 Aug 2020 18:02:43

FDA-CBER-2022-1614-0074250

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 15:35:24

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 15:35:24

FDA-CBER-2022-1614-0074252

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
DataPoint Activated.	System	08 Aug 2020 18:02:40
DataPoint Inactivated.	System	08 Aug 2020 18:02:37
Data entry locked.	System	07 Aug 2020 18:00:14
User entered 'Day 11'	System	07 Aug 2020 18:00:14

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-09T17:32:41', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '7b5eae38-8faa-4c08-8679-a0f0589dbbc1'	System	09 Aug 2020 23:32:46
User entered 'No (N)'	System	09 Aug 2020 23:32:46
DataPoint Activated.	System	08 Aug 2020 18:02:40
DataPoint Inactivated.	System	08 Aug 2020 18:02:37

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 11 Aug 2021 21:57:08
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-08-09T17:32:43', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '7b5eae38-8faa-4c08-8679-a0f0589dbbc1'	System	09 Aug 2020 23:32:46
User entered '09 Aug 2020 17:32'	System	09 Aug 2020 23:32:46
DataPoint Activated.	System	08 Aug 2020 18:02:40
DataPoint Inactivated.	System	08 Aug 2020 18:02:37

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
DataPoint Activated.	System	08 Aug 2020 18:02:40
DataPoint Inactivated.	System	08 Aug 2020 18:02:37
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 18:00:14

FDA-CBER-2022-1614-0074256

US3142013
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
DataPoint Activated.	System	08 Aug 2020 18:02:40
DataPoint Inactivated.	System	08 Aug 2020 18:02:37
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 18:00:14

FDA-CBER-2022-1614-0074257

US3142013
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4) (b) (4)	20 Aug 2020 19:55:46

US3142013
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '7 Aug 2020'	Dalia Jeronimo (b) (4) (b) (4)	20 Aug 2020 19:55:46

US3142013
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4) (b) (4)	20 Aug 2020 19:55:46

US3142013
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Dalia Jeronimo (b) (4) (b) (4)	20 Aug 2020 19:55:46

FDA-CBER-2022-1614-0074261

US3142013
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4) (b) (4)	20 Aug 2020 19:55:54

US3142013
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1'	System	20 Aug 2020 19:55:54

US3142013
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	24 Aug 2020 14:37:56

FDA-CBER-2022-1614-0074264

US3142013
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 13:43:57
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'First attempt made on the 14 AUG 2020 ' (Site from System).	Jami Wagner (b) (4) (b) (4)	24 Aug 2020 14:38:24
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	24 Aug 2020 14:37:56
User entered '18 Aug 2020'	Jami Wagner (b) (4) (b) (4)	24 Aug 2020 14:37:56

US3142013
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4) (b) (4)	24 Aug 2020 14:37:56

FDA-CBER-2022-1614-0074266

US3142013
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Jami Wagner (b) (4) (b) (4)	24 Aug 2020 14:37:56

FDA-CBER-2022-1614-0074267

US3142013
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	24 Aug 2020 14:38:40

US3142013
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1'	System	24 Aug 2020 14:38:40

US3142013
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	11 Dec 2020 18:26:06

US3142013
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	16 Dec 2020 03:44:11
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'INFORMATION IS PRESENTED CORRECTLY' (Site from System).	Jami Wagner (b) (4) (b) (4)	11 Dec 2020 18:26:45
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	11 Dec 2020 18:26:06
User entered '24 Aug 2020'	Jami Wagner (b) (4) (b) (4)	11 Dec 2020 18:26:06

US3142013
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4) (b) (4)	11 Dec 2020 18:26:06

FDA-CBER-2022-1614-0074272

US3142013
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Jami Wagner (b) (4) (b) (4)	11 Dec 2020 18:26:06

FDA-CBER-2022-1614-0074273

US3142013
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:21:41

US3142013
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1'	System	29 Sep 2020 23:21:41

US3142013
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:13:07

US3142013
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 15:22:36
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Information provided is correct- patient had illness symptoms during visit window and had to wait for resolution' (Site from System).	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:13:32
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	30 Sep 2020 00:13:07
User entered '29 Sep 2020'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:13:07

US3142013
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:13:07

US3142013
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'VISIT2'	System	30 Sep 2020 00:13:07

FDA-CBER-2022-1614-0074279

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Pre-Dose (PREDOSE)'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '29 Sep 2020'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '16:40'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '29 Sep 2020 16:40'	System	30 Sep 2020 00:16:38

FDA-CBER-2022-1614-0074284

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '97.3' F	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Other (Other)'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

FDA-CBER-2022-1614-0074286

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Temporal'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

FDA-CBER-2022-1614-0074287

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '86'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

FDA-CBER-2022-1614-0074288

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'bpm'	System	30 Sep 2020 00:16:38

FDA-CBER-2022-1614-0074289

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '14'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'breaths/min'	System	30 Sep 2020 00:16:38

FDA-CBER-2022-1614-0074291

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '120'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'mmHg'	System	30 Sep 2020 00:16:38

FDA-CBER-2022-1614-0074293

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '90'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

FDA-CBER-2022-1614-0074294

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:57:08
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'mmHg'	System	30 Sep 2020 00:16:38

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Post-Dose (POSTDOSE)'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

FDA-CBER-2022-1614-0074296

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '29 Sep 2020'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '17:33'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '29 Sep 2020 17:33'	System	30 Sep 2020 00:16:38

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '97.6' F	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Other (Other)'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Temporal'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '88'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'bpm'	System	30 Sep 2020 00:16:38

FDA-CBER-2022-1614-0074305

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '14'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

FDA-CBER-2022-1614-0074306

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'breaths/min'	System	30 Sep 2020 00:16:38

FDA-CBER-2022-1614-0074307

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '138'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'mmHg'	System	30 Sep 2020 00:16:38

FDA-CBER-2022-1614-0074309

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '84'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:38

US3142013
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:57:08
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'mmHg'	System	30 Sep 2020 00:16:38

US3142013
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:57:08
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:46

US3142013
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:57:08
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '29 Sep 2020'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:16:46

US3142013
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:19:50

FDA-CBER-2022-1614-0074314

US3142013
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '29 Sep 2020'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:19:50

US3142013
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Urine (URINE)'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:19:50

US3142013
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Negative (NEGATIVE)'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:19:50

US3142013
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
Query 'Per CDM : Pregnancy test was performed however, Was FSH sample collected is No. Kindly review and reconcile or provide explanation.' canceled (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 20:42:53
User opened query 'Per CDM : Pregnancy test was performed however, Was FSH sample collected is No. Kindly review and reconcile or provide explanation.' (Site from DM).		19 Mar 2021 14:27:11
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:19:50

FDA-CBER-2022-1614-0074318

US3142013
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:19:50

US3142013
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:19:50

US3142013
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:57:08
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	30 Sep 2020 00:19:50

FDA-CBER-2022-1614-0074321

US3142013
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:57:08
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:21:59

US3142013
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:57:08
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:21:59

US3142013
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:57:08
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:21:59

US3142013
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:57:08
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074325

US3142013
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:57:08
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '29 Sep 2020'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:21:59

US3142013
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:57:08
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '17:03'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:21:59

US3142013
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:57:08
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '29 Sep 2020 17:03'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074328

US3142013
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:57:08
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Left Arm (LEFT ARM)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:21:59

US3142013
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:57:08
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'ONCE'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074330

US3142013
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:57:08
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074331

US3142013
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:57:08
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:20:07

US3142013
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:57:08
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '29 Sep 2020'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:20:07

FDA-CBER-2022-1614-0074333

US3142013
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:57:08
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '16:54'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:20:07

US3142013
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:57:08
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '29 Sep 2020 16:54'	System	30 Sep 2020 00:20:07

US3142013
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 11 Aug 2021 21:57:08
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '29 Sep 2020'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:20:22

US3142013
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 21:57:08
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:20:22

US3142013
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 21:57:08
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:20:22

FDA-CBER-2022-1614-0074338

US3142013
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 21:57:08
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '16:46'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:20:22

FDA-CBER-2022-1614-0074339

US3142013
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 21:57:08
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '29 Sep 2020 16:46'	System	30 Sep 2020 00:20:22

US3142013
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 21:57:08
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:20:22

US3142013
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 21:57:08
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:20:22

US3142013
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 21:57:08
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '16:46'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 00:20:22

US3142013
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 21:57:08
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '29 Sep 2020 16:46'	System	30 Sep 2020 00:20:22

US3142013
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:22:04

FDA-CBER-2022-1614-0074345

US3142013
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1'	System	29 Sep 2020 23:22:04

FDA-CBER-2022-1614-0074346

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-29T18:29:47', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'fb185660-7d21-4d65-8eee-4b2c1577cbb1'	System	30 Sep 2020 16:28:21
User entered 'Yes (Y)'	System	30 Sep 2020 16:28:21

FDA-CBER-2022-1614-0074348

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-29T18:29:54', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'fb185660-7d21-4d65-8eee-4b2c1577cbb1'	System	30 Sep 2020 16:28:21
User entered '97.6'	System	30 Sep 2020 16:28:21

FDA-CBER-2022-1614-0074349

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-29T18:29:56', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'fb185660-7d21-4d65-8eee-4b2c1577cbb1'	System	30 Sep 2020 16:28:21
User entered 'No (N)'	System	30 Sep 2020 16:28:21

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-29T18:29:58', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'fb185660-7d21-4d65-8eee-4b2c1577cbb1'	System	30 Sep 2020 16:28:21
User entered '29 Sep 2020 18:29'	System	30 Sep 2020 16:28:21

FDA-CBER-2022-1614-0074351

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '29 Sep 2020 17:23'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074352

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '29 Sep 2020 19:53'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074353

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T10:28:48', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'a563957b-15f4-4ff2-ab19-c319dc6fb38f'	System	30 Sep 2020 16:29:00
User entered 'Yes (Y)'	System	30 Sep 2020 16:29:00

FDA-CBER-2022-1614-0074355

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T10:28:52', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'a563957b-15f4-4ff2-ab19-c319dc6fb38f'	System	30 Sep 2020 16:29:00
User entered '97.6'	System	30 Sep 2020 16:29:00

FDA-CBER-2022-1614-0074356

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T10:28:54', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'a563957b-15f4-4ff2-ab19-c319dc6fb38f'	System	30 Sep 2020 16:29:00
User entered 'No (N)'	System	30 Sep 2020 16:29:00

FDA-CBER-2022-1614-0074357

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T10:28:56', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'a563957b-15f4-4ff2-ab19-c319dc6fb38f'	System	30 Sep 2020 16:29:00
User entered '30 Sep 2020 10:28'	System	30 Sep 2020 16:29:00

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '29 Sep 2020 20:48'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074359

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074360

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 2'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:57:08
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T12:28:56', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '58b22174-ce60-42fe-b50f-113ef010e97c'	System	30 Sep 2020 18:29:38
User entered 'Yes (Y)'	System	30 Sep 2020 18:29:38

FDA-CBER-2022-1614-0074362

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:57:08
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T12:29:02', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '58b22174-ce60-42fe-b50f-113ef010e97c'	System	30 Sep 2020 18:29:38
User entered '98.5'	System	30 Sep 2020 18:29:38

FDA-CBER-2022-1614-0074363

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:57:08
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T12:29:06', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '58b22174-ce60-42fe-b50f-113ef010e97c'	System	30 Sep 2020 18:29:38
User entered 'Yes (Y)'	System	30 Sep 2020 18:29:38

FDA-CBER-2022-1614-0074364

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:57:08
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
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).		19 Nov 2020 06:17:24
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 'Subject was contacted. Medication is now listed under ConMed page. ' (Site from System).	Meghan York (b) (4) (b) (4)	17 Nov 2020 19:25:26
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	30 Sep 2020 18:29:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T12:29:28', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '58b22174-ce60-42fe-b50f-113ef010e97c'	System	30 Sep 2020 18:29:38
User entered '1'	System	30 Sep 2020 18:29:38

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:57:08
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T12:29:28', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '58b22174-ce60-42fe-b50f-113ef010e97c'	System	30 Sep 2020 18:29:38
User entered '0'	System	30 Sep 2020 18:29:38

FDA-CBER-2022-1614-0074366

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T12:29:32', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '58b22174-ce60-42fe-b50f-113ef010e97c'	System	30 Sep 2020 18:29:38
User entered '30 Sep 2020 12:29'	System	30 Sep 2020 18:29:38

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074368

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074369

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 3'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:57:08
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-01T12:00:10', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'bd2a27bd-51e7-40f5-a8a4-429fb4a3ecf4'	System	01 Oct 2020 18:00:26
User entered 'Yes (Y)'	System	01 Oct 2020 18:00:26

FDA-CBER-2022-1614-0074371

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:57:08
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-01T12:00:16', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'bd2a27bd-51e7-40f5-a8a4-429fb4a3ecf4'	System	01 Oct 2020 18:00:26
User entered '97.6'	System	01 Oct 2020 18:00:26

FDA-CBER-2022-1614-0074372

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:57:08
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-01T12:00:19', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'bd2a27bd-51e7-40f5-a8a4-429fb4a3ecf4'	System	01 Oct 2020 18:00:26
User entered 'No (N)'	System	01 Oct 2020 18:00:26

FDA-CBER-2022-1614-0074373

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-01T12:00:21', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'bd2a27bd-51e7-40f5-a8a4-429fb4a3ecf4'	System	01 Oct 2020 18:00:26
User entered '01 Oct 2020 12:00'	System	01 Oct 2020 18:00:26

FDA-CBER-2022-1614-0074374

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074375

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074376

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 4'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:57:08
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-03T08:06:34', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '0d2089c3-5c56-411f-8aaa-ac0645a6792e'	System	03 Oct 2020 14:06:45
User entered 'Yes (Y)'	System	03 Oct 2020 14:06:45

FDA-CBER-2022-1614-0074378

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:57:08
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-03T08:06:39', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '0d2089c3-5c56-411f-8aaa-ac0645a6792e'	System	03 Oct 2020 14:06:45
User entered '98.4'	System	03 Oct 2020 14:06:45

FDA-CBER-2022-1614-0074379

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:57:08
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-03T08:06:41', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '0d2089c3-5c56-411f-8aaa-ac0645a6792e'	System	03 Oct 2020 14:06:45
User entered 'No (N)'	System	03 Oct 2020 14:06:45

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-03T08:06:43', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '0d2089c3-5c56-411f-8aaa-ac0645a6792e'	System	03 Oct 2020 14:06:45
User entered '03 Oct 2020 08:06'	System	03 Oct 2020 14:06:45

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074382

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074383

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 5'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:57:08
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-04T09:35:31', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '048fa933-c6bf-4fcb-86c8-1c0271bf23d0'	System	04 Oct 2020 15:35:42
User entered 'Yes (Y)'	System	04 Oct 2020 15:35:42

FDA-CBER-2022-1614-0074385

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:57:08
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-04T09:35:35', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '048fa933-c6bf-4fcb-86c8-1c0271bf23d0'	System	04 Oct 2020 15:35:42
User entered '98.4'	System	04 Oct 2020 15:35:42

FDA-CBER-2022-1614-0074386

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:57:08
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-04T09:35:37', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '048fa933-c6bf-4fcb-86c8-1c0271bf23d0'	System	04 Oct 2020 15:35:42
User entered 'No (N)'	System	04 Oct 2020 15:35:42

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-04T09:35:39', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '048fa933-c6bf-4fcb-86c8-1c0271bf23d0'	System	04 Oct 2020 15:35:42
User entered '04 Oct 2020 09:35'	System	04 Oct 2020 15:35:42

FDA-CBER-2022-1614-0074388

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074389

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074390

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 6'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:57:08
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:57:08
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074393

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:57:08
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074394

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:57:08
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074395

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:57:08
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074396

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074397

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074398

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074399

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 7'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:57:08
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074401

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:57:08
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074402

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:57:08
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:57:08
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074404

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:57:08
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074405

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074406

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074407

US3142013
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074408

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-29T18:29:22', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'c52cff29-87a3-47cf-b0e4-9125cc5addef'	System	30 Sep 2020 16:28:20
User entered 'None (1)'	System	30 Sep 2020 16:28:20

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-29T18:29:26', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'c52cff29-87a3-47cf-b0e4-9125cc5addef'	System	30 Sep 2020 16:28:20
User entered 'No (N)'	System	30 Sep 2020 16:28:20

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-29T18:29:32', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'c52cff29-87a3-47cf-b0e4-9125cc5addef'	System	30 Sep 2020 16:28:20
User entered 'No (N)'	System	30 Sep 2020 16:28:20

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-29T18:29:37', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'c52cff29-87a3-47cf-b0e4-9125cc5addef'	System	30 Sep 2020 16:28:20
User entered 'None (1)'	System	30 Sep 2020 16:28:20

FDA-CBER-2022-1614-0074413

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-29T18:29:39', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'c52cff29-87a3-47cf-b0e4-9125cc5addef'	System	30 Sep 2020 16:28:20
User entered '29 Sep 2020 18:29'	System	30 Sep 2020 16:28:20

FDA-CBER-2022-1614-0074414

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '29 Sep 2020 17:23'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074415

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '29 Sep 2020 19:53'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074416

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T10:29:00', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'cadfdeac-a8b5-4c71-9db5-1b4526cff777'	System	30 Sep 2020 16:29:28
User entered 'None (1)'	System	30 Sep 2020 16:29:28

FDA-CBER-2022-1614-0074418

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T10:29:02', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'cadfdeac-a8b5-4c71-9db5-1b4526cff777'	System	30 Sep 2020 16:29:28
User entered 'No (N)'	System	30 Sep 2020 16:29:28

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T10:29:19', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'cadfdeac-a8b5-4c71-9db5-1b4526cff777'	System	30 Sep 2020 16:29:28
User entered 'No (N)'	System	30 Sep 2020 16:29:28

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T10:29:21', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'cadfdeac-a8b5-4c71-9db5-1b4526cff777'	System	30 Sep 2020 16:29:28
User entered 'None (1)'	System	30 Sep 2020 16:29:28

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T10:29:24', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'cadfdeac-a8b5-4c71-9db5-1b4526cff777'	System	30 Sep 2020 16:29:28
User entered '30 Sep 2020 10:29'	System	30 Sep 2020 16:29:28

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '29 Sep 2020 20:48'	System	29 Sep 2020 23:21:59

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US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 23:21:59

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US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 2'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T12:29:40', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'a63f6381-80ff-4f95-b6d3-1dfa6b213fdc'	System	30 Sep 2020 18:29:55
User entered 'None (1)'	System	30 Sep 2020 18:29:55

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:57:08
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T12:29:43', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'a63f6381-80ff-4f95-b6d3-1dfa6b213fdc'	System	30 Sep 2020 18:29:55
User entered 'No (N)'	System	30 Sep 2020 18:29:55

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:57:08
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T12:29:49', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'a63f6381-80ff-4f95-b6d3-1dfa6b213fdc'	System	30 Sep 2020 18:29:55
User entered 'No (N)'	System	30 Sep 2020 18:29:55

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T12:29:51', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'a63f6381-80ff-4f95-b6d3-1dfa6b213fdc'	System	30 Sep 2020 18:29:55
User entered 'None (1)'	System	30 Sep 2020 18:29:55

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T12:29:53', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'a63f6381-80ff-4f95-b6d3-1dfa6b213fdc'	System	30 Sep 2020 18:29:55
User entered '30 Sep 2020 12:29'	System	30 Sep 2020 18:29:55

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US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074431

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 23:21:59

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US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 3'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-01T12:00:25', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '641940c8-4749-4279-8f1f-a48c3f056c0c'	System	01 Oct 2020 18:00:39
User entered 'None (1)'	System	01 Oct 2020 18:00:39

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US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:57:08
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-01T12:00:27', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '641940c8-4749-4279-8f1f-a48c3f056c0c'	System	01 Oct 2020 18:00:39
User entered 'No (N)'	System	01 Oct 2020 18:00:39

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:57:08
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-01T12:00:29', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '641940c8-4749-4279-8f1f-a48c3f056c0c'	System	01 Oct 2020 18:00:39
User entered 'No (N)'	System	01 Oct 2020 18:00:39

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US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-01T12:00:32', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '641940c8-4749-4279-8f1f-a48c3f056c0c'	System	01 Oct 2020 18:00:39
User entered 'None (1)'	System	01 Oct 2020 18:00:39

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-01T12:00:33', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '641940c8-4749-4279-8f1f-a48c3f056c0c'	System	01 Oct 2020 18:00:39
User entered '01 Oct 2020 12:00'	System	01 Oct 2020 18:00:39

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 23:21:59

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US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 23:21:59

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US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 4'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-03T08:06:47', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '8b2ce365-e712-4b06-a8da-694b8696dd76'	System	03 Oct 2020 14:06:56
User entered 'None (1)'	System	03 Oct 2020 14:06:56

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:57:08
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-03T08:06:50', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '8b2ce365-e712-4b06-a8da-694b8696dd76'	System	03 Oct 2020 14:06:56
User entered 'No (N)'	System	03 Oct 2020 14:06:56

FDA-CBER-2022-1614-0074443

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:57:08
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-03T08:06:51', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '8b2ce365-e712-4b06-a8da-694b8696dd76'	System	03 Oct 2020 14:06:56
User entered 'No (N)'	System	03 Oct 2020 14:06:56

FDA-CBER-2022-1614-0074444

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-03T08:06:52', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '8b2ce365-e712-4b06-a8da-694b8696dd76'	System	03 Oct 2020 14:06:56
User entered 'None (1)'	System	03 Oct 2020 14:06:56

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-03T08:06:54', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '8b2ce365-e712-4b06-a8da-694b8696dd76'	System	03 Oct 2020 14:06:56
User entered '03 Oct 2020 08:06'	System	03 Oct 2020 14:06:56

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 23:21:59

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US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 23:21:59

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US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 5'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-04T09:35:22', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'ef6a04e8-3caa-4843-8971-71d8fe5160d7'	System	04 Oct 2020 15:35:33
User entered 'None (1)'	System	04 Oct 2020 15:35:33

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:57:08
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-04T09:35:24', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'ef6a04e8-3caa-4843-8971-71d8fe5160d7'	System	04 Oct 2020 15:35:33
User entered 'No (N)'	System	04 Oct 2020 15:35:33

FDA-CBER-2022-1614-0074451

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:57:08
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-04T09:35:25', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'ef6a04e8-3caa-4843-8971-71d8fe5160d7'	System	04 Oct 2020 15:35:33
User entered 'No (N)'	System	04 Oct 2020 15:35:33

FDA-CBER-2022-1614-0074452

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-04T09:35:26', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'ef6a04e8-3caa-4843-8971-71d8fe5160d7'	System	04 Oct 2020 15:35:33
User entered 'None (1)'	System	04 Oct 2020 15:35:33

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-04T09:35:27', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'ef6a04e8-3caa-4843-8971-71d8fe5160d7'	System	04 Oct 2020 15:35:33
User entered '04 Oct 2020 09:35'	System	04 Oct 2020 15:35:33

FDA-CBER-2022-1614-0074454

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074455

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 6'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074457

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

FDA-CBER-2022-1614-0074458

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:57:08
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074459

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:57:08
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

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US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

FDA-CBER-2022-1614-0074462

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

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US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074464

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074465

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074466

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 7'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

FDA-CBER-2022-1614-0074468

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:57:08
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074469

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

FDA-CBER-2022-1614-0074470

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:57:08
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074471

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

FDA-CBER-2022-1614-0074472

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

FDA-CBER-2022-1614-0074473

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:57:08
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074474

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074475

US3142013
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074476

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074477

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-29T18:28:48', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '511df399-0bd5-4dd8-9eb7-151c5b7bea5c'	System	30 Sep 2020 00:29:19
User entered 'None (0)'	System	30 Sep 2020 00:29:19

FDA-CBER-2022-1614-0074478

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-29T18:28:50', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '511df399-0bd5-4dd8-9eb7-151c5b7bea5c'	System	30 Sep 2020 00:29:19
User entered 'None (0)'	System	30 Sep 2020 00:29:19

FDA-CBER-2022-1614-0074479

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-29T18:28:52', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '511df399-0bd5-4dd8-9eb7-151c5b7bea5c'	System	30 Sep 2020 00:29:19
User entered 'None (0)'	System	30 Sep 2020 00:29:19

FDA-CBER-2022-1614-0074480

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-29T18:28:54', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '511df399-0bd5-4dd8-9eb7-151c5b7bea5c'	System	30 Sep 2020 00:29:19
User entered 'None (0)'	System	30 Sep 2020 00:29:19

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-29T18:29:02', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '511df399-0bd5-4dd8-9eb7-151c5b7bea5c'	System	30 Sep 2020 00:29:19
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	30 Sep 2020 00:29:19

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-29T18:29:12', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '511df399-0bd5-4dd8-9eb7-151c5b7bea5c'	System	30 Sep 2020 00:29:19
User entered 'Some interference with activity not requiring medical attention (2)'	System	30 Sep 2020 00:29:19

FDA-CBER-2022-1614-0074483

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-29T18:29:15', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '511df399-0bd5-4dd8-9eb7-151c5b7bea5c'	System	30 Sep 2020 00:29:19
User entered 'No (N)'	System	30 Sep 2020 00:29:19

FDA-CBER-2022-1614-0074484

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-29T18:29:17', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '511df399-0bd5-4dd8-9eb7-151c5b7bea5c'	System	30 Sep 2020 00:29:19
User entered '29 Sep 2020 18:29'	System	30 Sep 2020 00:29:19

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '29 Sep 2020 17:23'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074486

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '29 Sep 2020 19:53'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074487

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T10:28:20', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'beb63b2f-f65a-414d-a01e-a8329b029e4a'	System	30 Sep 2020 16:28:44
User entered 'No interference with activity (1)'	System	30 Sep 2020 16:28:44

FDA-CBER-2022-1614-0074489

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T10:28:23', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'beb63b2f-f65a-414d-a01e-a8329b029e4a'	System	30 Sep 2020 16:28:44
User entered 'Some interference with activity (2)'	System	30 Sep 2020 16:28:44

FDA-CBER-2022-1614-0074490

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T10:28:27', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'beb63b2f-f65a-414d-a01e-a8329b029e4a'	System	30 Sep 2020 16:28:44
User entered 'Some interference with activity (2)'	System	30 Sep 2020 16:28:44

FDA-CBER-2022-1614-0074491

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T10:28:30', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'beb63b2f-f65a-414d-a01e-a8329b029e4a'	System	30 Sep 2020 16:28:44
User entered 'Some interference with activity (2)'	System	30 Sep 2020 16:28:44

FDA-CBER-2022-1614-0074492

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T10:28:35', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'beb63b2f-f65a-414d-a01e-a8329b029e4a'	System	30 Sep 2020 16:28:44
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	30 Sep 2020 16:28:44

FDA-CBER-2022-1614-0074493

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T10:28:37', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'beb63b2f-f65a-414d-a01e-a8329b029e4a'	System	30 Sep 2020 16:28:44
User entered 'No interference with activity (1)'	System	30 Sep 2020 16:28:44

FDA-CBER-2022-1614-0074494

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T10:28:41', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'beb63b2f-f65a-414d-a01e-a8329b029e4a'	System	30 Sep 2020 16:28:44
User entered 'No (N)'	System	30 Sep 2020 16:28:44

FDA-CBER-2022-1614-0074495

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T10:28:43', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'beb63b2f-f65a-414d-a01e-a8329b029e4a'	System	30 Sep 2020 16:28:44
User entered '30 Sep 2020 10:28'	System	30 Sep 2020 16:28:44

FDA-CBER-2022-1614-0074496

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '29 Sep 2020 20:48'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074497

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074498

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 2'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T12:29:59', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '6bdfa76c-786f-47f1-ba5c-923cfe33706e'	System	30 Sep 2020 18:30:20
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	30 Sep 2020 18:30:20

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T12:30:02', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '6bdfa76c-786f-47f1-ba5c-923cfe33706e'	System	30 Sep 2020 18:30:20
User entered 'Some interference with activity (2)'	System	30 Sep 2020 18:30:20

FDA-CBER-2022-1614-0074501

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T12:30:07', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '6bdfa76c-786f-47f1-ba5c-923cfe33706e'	System	30 Sep 2020 18:30:20
User entered 'Some interference with activity (2)'	System	30 Sep 2020 18:30:20

FDA-CBER-2022-1614-0074502

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T12:30:08', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '6bdfa76c-786f-47f1-ba5c-923cfe33706e'	System	30 Sep 2020 18:30:20
User entered 'Some interference with activity (2)'	System	30 Sep 2020 18:30:20

FDA-CBER-2022-1614-0074503

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T12:30:10', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '6bdfa76c-786f-47f1-ba5c-923cfe33706e'	System	30 Sep 2020 18:30:20
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	30 Sep 2020 18:30:20

FDA-CBER-2022-1614-0074504

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T12:30:13', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '6bdfa76c-786f-47f1-ba5c-923cfe33706e'	System	30 Sep 2020 18:30:20
User entered 'No interference with activity (1)'	System	30 Sep 2020 18:30:20

FDA-CBER-2022-1614-0074505

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T12:30:15', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '6bdfa76c-786f-47f1-ba5c-923cfe33706e'	System	30 Sep 2020 18:30:20
User entered 'No (N)'	System	30 Sep 2020 18:30:20

FDA-CBER-2022-1614-0074506

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-30T12:30:18', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '6bdfa76c-786f-47f1-ba5c-923cfe33706e'	System	30 Sep 2020 18:30:20
User entered '30 Sep 2020 12:30'	System	30 Sep 2020 18:30:20

FDA-CBER-2022-1614-0074507

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074508

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074509

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 3'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-01T12:00:37', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '3925fe66-82a6-4484-a648-fe1cefe2a07f'	System	01 Oct 2020 18:00:57
User entered 'No interference with activity (1)'	System	01 Oct 2020 18:00:57

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-01T12:00:40', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '3925fe66-82a6-4484-a648-fe1cefe2a07f'	System	01 Oct 2020 18:00:57
User entered 'No interference with activity (1)'	System	01 Oct 2020 18:00:57

FDA-CBER-2022-1614-0074512

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-01T12:00:42', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '3925fe66-82a6-4484-a648-fe1cefe2a07f'	System	01 Oct 2020 18:00:57
User entered 'No interference with activity (1)'	System	01 Oct 2020 18:00:57

FDA-CBER-2022-1614-0074513

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-01T12:00:44', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '3925fe66-82a6-4484-a648-fe1cefe2a07f'	System	01 Oct 2020 18:00:57
User entered 'No interference with activity (1)'	System	01 Oct 2020 18:00:57

FDA-CBER-2022-1614-0074514

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-01T12:00:46', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '3925fe66-82a6-4484-a648-fe1cefe2a07f'	System	01 Oct 2020 18:00:57
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	01 Oct 2020 18:00:57

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-01T12:00:48', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '3925fe66-82a6-4484-a648-fe1cefe2a07f'	System	01 Oct 2020 18:00:57
User entered 'None (0)'	System	01 Oct 2020 18:00:57

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-01T12:00:51', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '3925fe66-82a6-4484-a648-fe1cefe2a07f'	System	01 Oct 2020 18:00:57
User entered 'No (N)'	System	01 Oct 2020 18:00:57

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-01T12:00:53', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '3925fe66-82a6-4484-a648-fe1cefe2a07f'	System	01 Oct 2020 18:00:57
User entered '01 Oct 2020 12:00'	System	01 Oct 2020 18:00:57

FDA-CBER-2022-1614-0074518

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074519

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 4'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-03T08:06:17', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'b2633f93-6eaa-40cd-a8fb-3c9bf21db8c4'	System	03 Oct 2020 14:06:31
User entered 'None (0)'	System	03 Oct 2020 14:06:31

FDA-CBER-2022-1614-0074522

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-03T08:06:19', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'b2633f93-6eaa-40cd-a8fb-3c9bf21db8c4'	System	03 Oct 2020 14:06:31
User entered 'None (0)'	System	03 Oct 2020 14:06:31

FDA-CBER-2022-1614-0074523

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-03T08:06:21', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'b2633f93-6eaa-40cd-a8fb-3c9bf21db8c4'	System	03 Oct 2020 14:06:31
User entered 'None (0)'	System	03 Oct 2020 14:06:31

FDA-CBER-2022-1614-0074524

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-03T08:06:22', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'b2633f93-6eaa-40cd-a8fb-3c9bf21db8c4'	System	03 Oct 2020 14:06:31
User entered 'None (0)'	System	03 Oct 2020 14:06:31

FDA-CBER-2022-1614-0074525

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-03T08:06:24', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'b2633f93-6eaa-40cd-a8fb-3c9bf21db8c4'	System	03 Oct 2020 14:06:31
User entered 'None (0)'	System	03 Oct 2020 14:06:31

FDA-CBER-2022-1614-0074526

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-03T08:06:25', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'b2633f93-6eaa-40cd-a8fb-3c9bf21db8c4'	System	03 Oct 2020 14:06:31
User entered 'None (0)'	System	03 Oct 2020 14:06:31

FDA-CBER-2022-1614-0074527

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-03T08:06:27', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'b2633f93-6eaa-40cd-a8fb-3c9bf21db8c4'	System	03 Oct 2020 14:06:31
User entered 'No (N)'	System	03 Oct 2020 14:06:31

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-03T08:06:29', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'b2633f93-6eaa-40cd-a8fb-3c9bf21db8c4'	System	03 Oct 2020 14:06:31
User entered '03 Oct 2020 08:06'	System	03 Oct 2020 14:06:31

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074530

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074531

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 5'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-04T09:35:10', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'a1b9e072-32a7-49ae-a0ec-22909c53128b'	System	04 Oct 2020 15:35:23
User entered 'None (0)'	System	04 Oct 2020 15:35:23

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-04T09:35:12', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'a1b9e072-32a7-49ae-a0ec-22909c53128b'	System	04 Oct 2020 15:35:23
User entered 'None (0)'	System	04 Oct 2020 15:35:23

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-04T09:35:13', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'a1b9e072-32a7-49ae-a0ec-22909c53128b'	System	04 Oct 2020 15:35:23
User entered 'None (0)'	System	04 Oct 2020 15:35:23

FDA-CBER-2022-1614-0074535

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-04T09:35:14', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'a1b9e072-32a7-49ae-a0ec-22909c53128b'	System	04 Oct 2020 15:35:23
User entered 'None (0)'	System	04 Oct 2020 15:35:23

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-04T09:35:15', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'a1b9e072-32a7-49ae-a0ec-22909c53128b'	System	04 Oct 2020 15:35:23
User entered 'None (0)'	System	04 Oct 2020 15:35:23

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-04T09:35:16', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'a1b9e072-32a7-49ae-a0ec-22909c53128b'	System	04 Oct 2020 15:35:23
User entered 'None (0)'	System	04 Oct 2020 15:35:23

FDA-CBER-2022-1614-0074538

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-04T09:35:18', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'a1b9e072-32a7-49ae-a0ec-22909c53128b'	System	04 Oct 2020 15:35:23
User entered 'No (N)'	System	04 Oct 2020 15:35:23

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-10-04T09:35:20', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: 'a1b9e072-32a7-49ae-a0ec-22909c53128b'	System	04 Oct 2020 15:35:23
User entered '04 Oct 2020 09:35'	System	04 Oct 2020 15:35:23

FDA-CBER-2022-1614-0074540

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074541

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074542

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 6'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074544

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074545

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074546

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074547

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074548

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074549

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

FDA-CBER-2022-1614-0074550

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074551

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074552

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	29 Sep 2020 23:21:59
User entered 'Day 7'	System	29 Sep 2020 23:21:59

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074555

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074556

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074557

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074558

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074559

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074560

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
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 01:22:21

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21

FDA-CBER-2022-1614-0074562

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 23:21:59

FDA-CBER-2022-1614-0074563

US3142013
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:57:08
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 23:21:59

US3142013
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	12 Oct 2020 22:55:31

US3142013
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '9 Oct 2020'	Jami Wagner (b) (4) (b) (4)	12 Oct 2020 22:55:31

US3142013
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4) (b) (4)	12 Oct 2020 22:55:31

FDA-CBER-2022-1614-0074567

US3142013
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Jami Wagner (b) (4) (b) (4)	12 Oct 2020 22:55:31

US3142013
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	12 Oct 2020 22:55:42

FDA-CBER-2022-1614-0074569

US3142013
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1'	System	12 Oct 2020 22:55:42

FDA-CBER-2022-1614-0074570

US3142013
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	13 Oct 2020 19:10:58

US3142013
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '13 Oct 2020'	Jami Wagner (b) (4) (b) (4)	13 Oct 2020 19:10:58

US3142013
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4) (b) (4)	13 Oct 2020 19:10:58

US3142013
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Jami Wagner (b) (4) (b) (4)	13 Oct 2020 19:10:58

FDA-CBER-2022-1614-0074574

US3142013
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	13 Oct 2020 19:11:08

US3142013
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1'	System	13 Oct 2020 19:11:08

FDA-CBER-2022-1614-0074576

US3142013
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4) (b) (4)	27 Oct 2020 19:02:48

US3142013
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
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)	02 Nov 2020 10:00:18
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 'Information is correct ' (Site from System).	Meghan York (b) (4) (b) (4)	27 Oct 2020 19:09:28
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	27 Oct 2020 19:02:48
User entered '26 Oct 2020'	Dalia Jeronimo (b) (4) (b) (4)	27 Oct 2020 19:02:48

US3142013
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4) (b) (4)	27 Oct 2020 19:02:48

FDA-CBER-2022-1614-0074579

US3142013
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Dalia Jeronimo (b) (4) (b) (4)	27 Oct 2020 19:02:48

FDA-CBER-2022-1614-0074580

US3142013
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4) (b) (4)	27 Oct 2020 19:02:54

US3142013
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1'	System	27 Oct 2020 19:02:54

FDA-CBER-2022-1614-0074582

US3142013
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:22:36

FDA-CBER-2022-1614-0074583

US3142013
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '30 Oct 2020'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:22:36

US3142013
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:22:36

FDA-CBER-2022-1614-0074585

US3142013
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'VISIT3'	System	04 Nov 2020 19:22:36

FDA-CBER-2022-1614-0074586

US3142013
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User closed query 'Per CDM: Vital signs is performed on 30 Oct 2020 for Visit 3 Day 57 as well as Illness Visit Day 1 , kindly review if they are duplicates else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 10:59:36
Query 'Per CDM: Vital signs is performed on 30 Oct 2020 for Visit 3 Day 57 as well as Illness Visit Day 1 , kindly review if they are duplicates else clarify.' answered with 'subject had two visits on the same day - both a day 57 and an illness visit' (Site from DM).	Jill York (b) (4)	01 Mar 2021 02:27:31
User opened query 'Per CDM: Vital signs is performed on 30 Oct 2020 for Visit 3 Day 57 as well as Illness Visit Day 1 , kindly review if they are duplicates else clarify.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 15:04:38
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:37:21

US3142013
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '30 Oct 2020'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:37:21

FDA-CBER-2022-1614-0074588

US3142013
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '09:08'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:37:21

US3142013
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '30 Oct 2020 09:08'	System	04 Nov 2020 19:37:21

US3142013
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '97.2' F	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:37:21

US3142013
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Other (Other)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:37:21

FDA-CBER-2022-1614-0074592

US3142013
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Temporal'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:37:21

FDA-CBER-2022-1614-0074593

US3142013
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '94'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:37:21

US3142013
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'bpm'	System	04 Nov 2020 19:37:21

FDA-CBER-2022-1614-0074595

US3142013
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '14'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:37:21

US3142013
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'breaths/min'	System	04 Nov 2020 19:37:21

FDA-CBER-2022-1614-0074597

US3142013
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '130'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:37:21

FDA-CBER-2022-1614-0074598

US3142013
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'mmHg'	System	04 Nov 2020 19:37:21

FDA-CBER-2022-1614-0074599

US3142013
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '81'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:37:21

US3142013
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'mmHg'	System	04 Nov 2020 19:37:21

FDA-CBER-2022-1614-0074601

US3142013
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074602

US3142013
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074603

US3142013
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:57:08
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:37:32

US3142013
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:57:08
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '30 Oct 2020'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:37:32

US3142013
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:57:08
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:37:44

FDA-CBER-2022-1614-0074606

US3142013
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:57:08
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered '30 Oct 2020'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:37:44

US3142013
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:57:08
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 21:25:47
User entered '9:24' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	10 Nov 2020 21:25:47
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Nov 2020 19:37:44
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:37:44

US3142013
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:57:08
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '30 Oct 2020 9:24'	System	10 Nov 2020 21:25:47
User entered empty.	System	04 Nov 2020 19:37:44

US3142013
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:55:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:37:51

FDA-CBER-2022-1614-0074610

US3142013
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1'	System	04 Nov 2020 19:37:51

FDA-CBER-2022-1614-0074611

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 64'	System	31 Jul 2020 17:44:32

US3142013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-29T18:28:36', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '37227d82-5d65-4cc7-bcb1-9a185c2e83a0'	System	30 Sep 2020 00:28:44
User entered 'No (N)'	System	30 Sep 2020 00:28:44

US3142013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-29T18:28:38', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '37227d82-5d65-4cc7-bcb1-9a185c2e83a0'	System	30 Sep 2020 00:28:44
User entered 'No (N)'	System	30 Sep 2020 00:28:44

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C71466BD-93B1-4616-ADB1-24CD9E366705)', Time: '2020-09-29T18:28:42', User OID: 'PatientReportedOutcome (US3142013)', ODM File OID: '37227d82-5d65-4cc7-bcb1-9a185c2e83a0'	System	30 Sep 2020 00:28:44
User entered '29 Sep 2020 18:28:42'	System	30 Sep 2020 00:28:44

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered '29 Sep 2020 00:01'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074616

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:22:21
Data entry locked.	System	31 Jul 2020 17:44:32
User entered '03 Oct 2020 23:59'	System	31 Jul 2020 17:44:32

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 71'	System	31 Jul 2020 17:44:32

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074620

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074621

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074622

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074640

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074641

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19
Data entry locked.	System	31 Jul 2020 17:44:32
User entered '06 Oct 2020 00:01'	System	31 Jul 2020 17:44:32

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19
Data entry locked.	System	31 Jul 2020 17:44:32
User entered '10 Oct 2020 23:59'	System	31 Jul 2020 17:44:32

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 78'	System	31 Jul 2020 17:44:32

US3142013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074649

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074650

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074668

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074669

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074670

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19
Data entry locked.	System	31 Jul 2020 17:44:32
User entered '13 Oct 2020 00:01'	System	31 Jul 2020 17:44:32

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19
Data entry locked.	System	31 Jul 2020 17:44:32
User entered '17 Oct 2020 23:59'	System	31 Jul 2020 17:44:32

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 92'	System	31 Jul 2020 17:44:32

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074675

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074678

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074697

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074698

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19
Data entry locked.	System	31 Jul 2020 17:44:32
User entered '27 Oct 2020 00:01'	System	31 Jul 2020 17:44:32

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19
Data entry locked.	System	31 Jul 2020 17:44:32
User entered '31 Oct 2020 23:59'	System	31 Jul 2020 17:44:32

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 99'	System	31 Jul 2020 17:44:32

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074706

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074724

US3142013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074726

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074727

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19
Data entry locked.	System	31 Jul 2020 17:44:32
User entered '03 Nov 2020 00:01'	System	31 Jul 2020 17:44:32

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19
Data entry locked.	System	31 Jul 2020 17:44:32
User entered '07 Nov 2020 23:59'	System	31 Jul 2020 17:44:32

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 106'	System	31 Jul 2020 17:44:32

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074731

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074733

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074734

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074752

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074753

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074754

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074755

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19
Data entry locked.	System	31 Jul 2020 17:44:32
User entered '10 Nov 2020 00:01'	System	31 Jul 2020 17:44:32

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19
Data entry locked.	System	31 Jul 2020 17:44:32
User entered '14 Nov 2020 23:59'	System	31 Jul 2020 17:44:32

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19
Data entry locked.	System	31 Jul 2020 17:44:32
User entered 'Day 113'	System	31 Jul 2020 17:44:32

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074759

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074761

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074762

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074780

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074781

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074782

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074783

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19
Data entry locked.	System	31 Jul 2020 17:44:32
User entered '17 Nov 2020 00:01'	System	31 Jul 2020 17:44:32

US3142013
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:38:19
Data entry locked.	System	31 Jul 2020 17:44:32
User entered '21 Nov 2020 23:59'	System	31 Jul 2020 17:44:32

FDA-CBER-2022-1614-0074785

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 10:38:19

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074792

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074793

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074795

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074796

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074798

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074802

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074805

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074806

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074812

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 10:38:19

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074823

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074825

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074827

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074831

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074833

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074834

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074840

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 10:38:19

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074851

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074852

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074853

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074855

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074858

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074860

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074861

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074862

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074868

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 10:38:19

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074876

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074878

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074883

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074889

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074890

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 10:38:19

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074905

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074907

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074910

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074911

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074912

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074916

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074917

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074918

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074923

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074924

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074925

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 10:38:19

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074932

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074933

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074934

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074935

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074936

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074937

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074939

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074942

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074945

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074946

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 10:38:19

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074958

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074960

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074961

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074962

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074963

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074964

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074965

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074967

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074971

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074972

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074973

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074974

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0074980

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074983

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074988

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074990

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074991

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074992

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074993

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074994

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074995

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074996

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0074999

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075001

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075002

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 10:38:19

FDA-CBER-2022-1614-0075009

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 10:38:19

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075016

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075017

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075018

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075021

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075022

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075023

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075024

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075030

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075031

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075042

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075044

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075046

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075047

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075048

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075051

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075055

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075056

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075058

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075063

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 10:38:19

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075072

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075073

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075074

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075075

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075086

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075095

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075102

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075104

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075106

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075107

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075111

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075113

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075114

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 10:38:19

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075128

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075130

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075131

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075132

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075135

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075136

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075139

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075141

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075142

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075143

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075147

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 10:38:19

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

Have you been exposed to someone with 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075156

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075157

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075158

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075162

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075163

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075167

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075170

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17

US3142013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:08

Please 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)	27 Apr 2021 04:03:17

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075175

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 10:38:19

US3142013
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:57:08
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:19
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 10:38:19

US3142013
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	14 Dec 2020 21:49:40

US3142013
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	16 Dec 2020 05:07:40
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'INFORMATION IS PRESENTED CORRECTLY' (Site from System).	Jami Wagner (b) (4) (b) (4)	14 Dec 2020 21:50:54
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Dec 2020 21:49:40
User entered '20 Nov 2020'	Jami Wagner (b) (4) (b) (4)	14 Dec 2020 21:49:40

US3142013
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jami Wagner (b) (4) (b) (4)	14 Dec 2020 21:49:40

US3142013
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'LEFT MESSAGE'	Jami Wagner (b) (4) (b) (4)	14 Dec 2020 21:49:40

FDA-CBER-2022-1614-0075181

US3142013
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	14 Dec 2020 21:48:21

US3142013
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1'	System	14 Dec 2020 21:48:21

FDA-CBER-2022-1614-0075183

US3142013
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Lisa Jackson (b) (4) (b) (4)	26 Feb 2021 18:42:04

US3142013
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	26 Feb 2021 18:42:04

US3142013
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	26 Feb 2021 18:42:04

US3142013
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	26 Feb 2021 18:42:04

FDA-CBER-2022-1614-0075187

US3142013
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	12 Feb 2021 19:14:34

US3142013
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1'	System	12 Feb 2021 19:14:34

FDA-CBER-2022-1614-0075189

US3142013
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	12 Feb 2021 19:15:02

US3142013
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
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)	23 Feb 2021 07:55:45
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).	Jill York (b) (4)	16 Feb 2021 17:36:55
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	12 Feb 2021 19:15:02
User entered '3 Feb 2021'	Jami Wagner (b) (4) (b) (4)	12 Feb 2021 19:15:02

US3142013
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jami Wagner (b) (4) (b) (4)	12 Feb 2021 19:15:02

US3142013
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Voice mail not set up'	Jami Wagner (b) (4) (b) (4)	12 Feb 2021 19:15:02

FDA-CBER-2022-1614-0075193

US3142013
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	12 Feb 2021 19:15:07

US3142013
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1'	System	12 Feb 2021 19:15:07

FDA-CBER-2022-1614-0075195

US3142013
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	18 Mar 2021 21:50:29
User entered 'No (N)'	Lisa Jackson (b) (4) (b) (4)	26 Feb 2021 18:42:23

US3142013
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '26 Feb 2021' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	18 Mar 2021 21:50:29
User entered empty.	Lisa Jackson (b) (4) (b) (4)	26 Feb 2021 18:42:23

US3142013
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	18 Mar 2021 21:50:29
User entered empty.	Lisa Jackson (b) (4) (b) (4)	26 Feb 2021 18:42:23

US3142013
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:57:08
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Lisa Jackson (b) (4) (b) (4)	26 Feb 2021 18:42:23

US3142013
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	23 Mar 2021 15:17:44
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	26 Feb 2021 18:43:07

US3142013
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:57:08
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	23 Mar 2021 15:17:44
User entered '1'	System	26 Feb 2021 18:43:07

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 21:57:08
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:13:13
DataPoint Un-verified.		02 Feb 2021 16:12:57
DataPoint Verified.		02 Feb 2021 16:09:24
User closed query 'Per CDM: Multiple covid-19 assessments in sequential date order have been completed. Please reconcile and complete per the CCGs.' (Site from DM).		09 Nov 2020 00:53:12
Query 'Per CDM: Multiple covid-19 assessments in sequential date order have been completed. Please reconcile and complete per the CCGs.' answered with 'Need to be condensed to a single page. ' (Site from DM).	Shelby Pickle (b) (4) (b) (4)	28 Oct 2020 16:19:50
User opened query 'Per CDM: Multiple covid-19 assessments in sequential date order have been completed. Please reconcile and complete per the CCGs.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 03:06:38
DataPoint Un-verified.		02 Oct 2020 17:55:09
DataPoint Verified.		30 Sep 2020 19:44:49
User entered '19 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	19 Aug 2020 20:08:47

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 21:57:08
Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:09:44
DataPoint Un-verified.		02 Oct 2020 17:55:10
DataPoint Verified.		30 Sep 2020 19:44:57
User entered '13:40'	Shelby Pickle (b) (4) (b) (4)	19 Aug 2020 20:08:47

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 21:57:08
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '19 Aug 2020 13:40'	System	19 Aug 2020 20:08:47

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 21:57:08
Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:13:25
DataPoint Un-verified.		02 Feb 2021 16:13:00
DataPoint Verified.		02 Feb 2021 16:09:53
DataPoint Un-verified.		02 Oct 2020 17:55:12
DataPoint Verified.		02 Oct 2020 17:27:54
User closed query 'please confirm if this was a scheduled or unscheduled visit' (Site from CRA).		30 Sep 2020 19:44:51
Query 'please confirm if this was a scheduled or unscheduled visit' answered with 'scheduled ' (Site from CRA).	Meghan York (b) (4) (b) (4)	29 Sep 2020 17:24:13
User opened query 'please confirm if this was a scheduled or unscheduled visit' (Site from CRA).	(b) (4), (b) (6)	20 Aug 2020 03:21:02
User entered 'Clinic Visit - Scheduled (Clinic Visit Scheduled)'	Shelby Pickle (b) (4) (b) (4)	19 Aug 2020 20:08:47

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 21:57:08
Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:13:29
DataPoint Un-verified.		02 Feb 2021 16:13:02
DataPoint Verified.		02 Feb 2021 16:10:01
DataPoint Un-verified.		02 Oct 2020 17:55:13
DataPoint Verified.		30 Sep 2020 19:45:03
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	19 Aug 2020 20:08:47

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 1 (Day 1)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:14:09
User entered '19 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:14:11
User entered '0'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

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US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:14:15
User closed query 'Per CDM: it appears subject as </= 93% saturation recorded in Symptom Log Day 1 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' (Site from DM).		05 Nov 2020 16:43:51
Query 'Per CDM: it appears subject as </= 93% saturation recorded in Symptom Log Day 1 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' answered with 'Unsure what the query is' (Site from DM).	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:52:47
User opened query 'Per CDM: it appears subject as </= 93% saturation recorded in Symptom Log Day 1 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 14:11:09
User entered '91'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

FDA-CBER-2022-1614-0075210

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '%'	System	31 Aug 2020 16:16:57

FDA-CBER-2022-1614-0075211

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:14:21
User entered '97.0' F	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

FDA-CBER-2022-1614-0075212

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:14:23
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		20 Apr 2021 23:10:23
User closed query 'Please provide SD for severity of symptoms.' (Site from CRA).		20 Apr 2021 23:08:13
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
Query 'Please provide SD for severity of symptoms.' answered with 'See Illness visit One on 19 Aug 2020' (Site from CRA).	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 18:41:28
User opened query 'Please provide SD for severity of symptoms.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:18:49
DataPoint Un-verified.		02 Feb 2021 16:16:07
DataPoint Verified.		02 Feb 2021 16:15:16
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

FDA-CBER-2022-1614-0075214

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		20 Apr 2021 23:10:23
User closed query 'Please provide SD for severity of symptoms.' (Site from CRA).		20 Apr 2021 23:08:28
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
Query 'Please provide SD for severity of symptoms.' answered with 'See Illness visit One on 19 Aug 2020' (Site from CRA).	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 18:41:40
User opened query 'Please provide SD for severity of symptoms.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:19:09
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User closed query 'Please provide SD for severity of symptoms.' (Site from CRA).		20 Apr 2021 23:09:10
DataPoint Verified.		20 Apr 2021 23:08:51
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
Query 'Please provide SD for severity of symptoms.' answered with 'See Illness visit One on 19 Aug 2020' (Site from CRA).	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 18:41:53
User opened query 'Please provide SD for severity of symptoms.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:22:16
DataPoint Un-verified.		02 Feb 2021 16:19:19
DataPoint Verified.		02 Feb 2021 16:19:14
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

FDA-CBER-2022-1614-0075216

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		20 Apr 2021 23:10:23
User closed query 'Please provide SD for severity of symptoms.' (Site from CRA).		20 Apr 2021 23:09:25
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
Query 'Please provide SD for severity of symptoms.' answered with 'See Illness visit One on 19 Aug 2020' (Site from CRA).	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 18:42:07
User opened query 'Please provide SD for severity of symptoms.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:22:20
DataPoint Un-verified.		02 Feb 2021 16:19:39
DataPoint Verified.		02 Feb 2021 16:19:34
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

FDA-CBER-2022-1614-0075217

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		20 Apr 2021 23:10:23
User closed query 'Please provide SD for severity of symptoms.' (Site from CRA).		20 Apr 2021 23:09:36
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
Query 'Please provide SD for severity of symptoms.' answered with 'See Illness visit One on 19 Aug 2020' (Site from CRA).	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 18:43:44
User opened query 'Please provide SD for severity of symptoms.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:22:24
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

FDA-CBER-2022-1614-0075218

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		20 Apr 2021 23:10:23
User closed query 'Please provide SD for severity of symptoms.' (Site from CRA).		20 Apr 2021 23:09:50
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
Query 'Please provide SD for severity of symptoms.' answered with 'See Illness visit One on 19 Aug 2020' (Site from CRA).	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 18:40:58
User opened query 'Please provide SD for severity of symptoms.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:22:27
DataPoint Un-verified.		02 Feb 2021 16:20:24
DataPoint Verified.		02 Feb 2021 16:20:20
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

FDA-CBER-2022-1614-0075219

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		20 Apr 2021 23:10:23
User closed query 'Please provide SD for severity of symptoms.' (Site from CRA).		20 Apr 2021 23:10:07
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
Query 'Please provide SD for severity of symptoms.' answered with 'See Illness visit One on 19 Aug 2020' (Site from CRA).	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 18:32:05
User opened query 'Please provide SD for severity of symptoms.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:22:31
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

FDA-CBER-2022-1614-0075220

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		20 Apr 2021 23:10:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

FDA-CBER-2022-1614-0075221

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		20 Apr 2021 23:10:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

FDA-CBER-2022-1614-0075222

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		20 Apr 2021 23:10:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

FDA-CBER-2022-1614-0075223

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User closed query 'Please provide SD for severity of symptoms.' (Site from CRA).		20 Apr 2021 23:10:53
DataPoint Verified.		20 Apr 2021 23:10:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
Query 'Please provide SD for severity of symptoms.' answered with 'See Illness visit One on 19 Aug 2020' (Site from CRA).	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 18:43:31
User opened query 'Please provide SD for severity of symptoms.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:22:39
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

FDA-CBER-2022-1614-0075224

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User closed query 'Please provide SD for severity of symptoms.' (Site from CRA).		20 Apr 2021 23:11:06
DataPoint Verified.		20 Apr 2021 23:10:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
Query 'Please provide SD for severity of symptoms.' answered with 'See Illness visit One on 19 Aug 2020' (Site from CRA).	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 18:43:13
User opened query 'Please provide SD for severity of symptoms.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:23:05
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		20 Apr 2021 23:10:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

FDA-CBER-2022-1614-0075226

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		20 Apr 2021 23:10:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

FDA-CBER-2022-1614-0075227

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User closed query 'Please provide SD for severity of symptoms.' (Site from CRA).		20 Apr 2021 23:10:36
DataPoint Verified.		20 Apr 2021 23:10:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
Query 'Please provide SD for severity of symptoms.' answered with 'See Illness visit One on 19 Aug 2020' (Site from CRA).	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 18:42:57
User opened query 'Please provide SD for severity of symptoms.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:23:15
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:16:57

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 2 (Day 2)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

FDA-CBER-2022-1614-0075229

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:24:16
User entered '20 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:24:23
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:24:26
User entered '95'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '%'	System	04 Nov 2020 18:58:30

FDA-CBER-2022-1614-0075233

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:24:31
User entered '99.8' F	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:24:34
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:24:44
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:24:51
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		20 Apr 2021 23:10:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

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US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:27:22
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

FDA-CBER-2022-1614-0075239

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:27:27
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:28:30
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

FDA-CBER-2022-1614-0075241

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:28:23
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:28:37
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:28:46
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:28:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:03
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

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US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:05
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:08
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:15
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

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US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:18
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 18:58:30

FDA-CBER-2022-1614-0075250

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 3 (Day 3)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

FDA-CBER-2022-1614-0075251

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:30:31
User entered '21 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

FDA-CBER-2022-1614-0075252

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:30:35
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:30:41
User entered '95'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

FDA-CBER-2022-1614-0075254

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '%'	System	04 Nov 2020 19:04:28

FDA-CBER-2022-1614-0075255

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:30:44
User entered '99.1' F	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

FDA-CBER-2022-1614-0075256

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User closed query 'Please verify if chills were assessed as there is no notation on SD.' (Site from CRA).		20 Apr 2021 23:11:54
DataPoint Verified.		20 Apr 2021 23:10:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
Query 'Please verify if chills were assessed as there is no notation on SD.' answered with 'see telemedicine visit 21 Aug 2020 SD' (Site from CRA).	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 18:49:42
User opened query 'Please verify if chills were assessed as there is no notation on SD.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:33:28
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:39
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:33:45
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

FDA-CBER-2022-1614-0075259

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User closed query '"Difficulty breathing" is not noted in SD. Please verify' (Site from CRA).		20 Apr 2021 23:12:06
DataPoint Verified.		20 Apr 2021 23:10:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
Query '"Difficulty breathing" is not noted in SD. Please verify' answered with 'NOT ASSESSED' (Site from CRA).	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 18:49:30
User opened query '"Difficulty breathing" is not noted in SD. Please verify' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:36:42
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:37:19
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

FDA-CBER-2022-1614-0075261

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:37:26
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

FDA-CBER-2022-1614-0075262

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:37:39
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:37:44
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

FDA-CBER-2022-1614-0075264

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:38:00
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:38:02
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

FDA-CBER-2022-1614-0075266

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:38:06
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

FDA-CBER-2022-1614-0075267

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:38:12
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:38:19
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:38:26
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

FDA-CBER-2022-1614-0075270

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:38:28
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:38:31
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:04:28

FDA-CBER-2022-1614-0075272

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 4 (Day 4)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

FDA-CBER-2022-1614-0075273

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:39:00
User entered '22 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		20 Apr 2021 23:10:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:39:09
User entered '95'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

FDA-CBER-2022-1614-0075276

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '%'	System	04 Nov 2020 19:10:28

FDA-CBER-2022-1614-0075277

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:39:12
User entered '99.6' F	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

FDA-CBER-2022-1614-0075278

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:39:17
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:39:29
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

FDA-CBER-2022-1614-0075280

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:39:34
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User closed query 'Please verify if difficulty breathing was assessed as there is no notation in SD,' (Site from CRA).		20 Apr 2021 23:12:54
DataPoint Verified.		20 Apr 2021 23:10:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
Query 'Please verify if difficulty breathing was assessed as there is no notation in SD,' answered with 'Not assessed on 22Aug 2020' (Site from CRA).	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 19:20:00
User entered 'None (None)' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 19:19:12
User opened query 'Please verify if difficulty breathing was assessed as there is no notation in SD, (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:41:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

FDA-CBER-2022-1614-0075282

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:42:14
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

FDA-CBER-2022-1614-0075283

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:42:19
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

FDA-CBER-2022-1614-0075284

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:43:08
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

FDA-CBER-2022-1614-0075285

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:43:19
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

FDA-CBER-2022-1614-0075286

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:43:28
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:43:31
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:43:48
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:43:52
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:43:55
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:44:02
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

FDA-CBER-2022-1614-0075292

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:44:07
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

FDA-CBER-2022-1614-0075293

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:44:09
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:10:28

FDA-CBER-2022-1614-0075294

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 5 (Day 5)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:44:26
User entered '23 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:44:30
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

FDA-CBER-2022-1614-0075297

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:44:40
User entered '95'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '%'	System	04 Nov 2020 19:12:12

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:44:44
User entered '99.3' F	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User closed query 'Please verify if "Chills" was assessed as it is not noted in SD.' (Site from CRA).		20 Apr 2021 23:13:39
DataPoint Verified.		20 Apr 2021 23:10:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
Query 'Please verify if "Chills" was assessed as it is not noted in SD.' answered with 'Patient confirmed no chills as documented from telemedicine visit SD 23 Aug 2020' (Site from CRA).	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 19:31:57
User opened query 'Please verify if "Chills" was assessed as it is not noted in SD.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:46:51
DataPoint Un-verified.		02 Feb 2021 16:45:36
DataPoint Verified.		02 Feb 2021 16:45:34
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

FDA-CBER-2022-1614-0075301

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:47:04
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:47:11
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User closed query 'Please verify if "difficulty breathing" was assessed as it is not noted in the SD' (Site from CRA).		20 Apr 2021 23:13:51
DataPoint Verified.		20 Apr 2021 23:10:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
Query 'Please verify if "difficulty breathing" was assessed as it is not noted in the SD' answered with 'not assessed' (Site from CRA).	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 19:37:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 19:36:40
User opened query 'Please verify if "difficulty breathing" was assessed as it is not noted in the SD' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:48:42
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

FDA-CBER-2022-1614-0075304

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:48:52
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

FDA-CBER-2022-1614-0075305

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:48:56
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:49:01
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

FDA-CBER-2022-1614-0075307

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:49:05
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:49:11
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:49:14
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:49:29
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

FDA-CBER-2022-1614-0075311

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:49:33
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

FDA-CBER-2022-1614-0075312

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:49:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:49:40
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:49:46
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:49:51
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:12:12

FDA-CBER-2022-1614-0075316

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 6 (Day 6)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

FDA-CBER-2022-1614-0075317

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:50:34
User entered '24 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:50:37
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

FDA-CBER-2022-1614-0075319

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:50:59
User entered '96'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '%'	System	04 Nov 2020 19:13:42

FDA-CBER-2022-1614-0075321

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:51:01
User entered '99.5' F	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

FDA-CBER-2022-1614-0075322

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:51:08
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:51:10
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:51:15
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:51:26
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:51:29
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

FDA-CBER-2022-1614-0075327

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:51:32
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:51:53
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:52:00
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:52:05
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:52:07
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:52:12
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:52:17
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:52:20
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:52:22
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

FDA-CBER-2022-1614-0075336

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:52:24
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:52:29
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:13:42

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08
Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:01:02
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '19 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	19 Aug 2020 20:09:33

FDA-CBER-2022-1614-0075339

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08
Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:01:02
User signature succeeded.		18 Apr 2021 18:54:52
User closed query 'Per GCL Lab Recon Requery: Please complete an Illness Visit.' (Site from DM).		23 Nov 2020 10:02:20
Query 'Per GCL Lab Recon Requery: Please complete an Illness Visit.' answered with 'Illness visit added.' (Site from DM).	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:19:39
User opened query 'Per GCL Lab Recon Requery: Please complete an Illness Visit.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 14:10:23
User closed query 'Per GCL Lab Recon: GCL has a SARS sample dated 19Aug2020, however, no Illness visit has been completed. Please reconcile.' (Site from DM).		30 Oct 2020 14:10:23
Query 'Per GCL Lab Recon: GCL has a SARS sample dated 19Aug2020, however, no Illness visit has been completed. Please reconcile.' answered with 'Patient came in for an illness visit on 19Aug2020. Information correct. Patient tested negative ' (Site from DM).	Shelby Pickle (b) (4) (b) (4)	28 Oct 2020 16:19:12
User opened query 'Per GCL Lab Recon: GCL has a SARS sample dated 19Aug2020, however, no Illness visit has been completed. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 03:09:02
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	19 Aug 2020 20:09:33

FDA-CBER-2022-1614-0075340

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:01:02
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 16:17:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 16:17:24
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:17:24
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 20:09:33
User entered empty.	Shelby Pickle (b) (4) (b) (4)	19 Aug 2020 20:09:33

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08
Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:01:02
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 16:17:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 16:17:24
User entered '19 Aug 2020' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:17:24
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 20:09:33
User entered empty.	Shelby Pickle (b) (4) (b) (4)	19 Aug 2020 20:09:33

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08
Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:01:02
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 16:17:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 16:17:24
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:17:24
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 20:09:33
User entered empty.	Shelby Pickle (b) (4) (b) (4)	19 Aug 2020 20:09:33

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08
Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:01:02
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	19 Aug 2020 20:09:33

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08

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)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:01:02
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:17:24
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:24:12

FDA-CBER-2022-1614-0075345

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08
Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:01:02
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	19 Aug 2020 20:09:33

FDA-CBER-2022-1614-0075346

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08
CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:01:02
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	19 Aug 2020 20:09:33

FDA-CBER-2022-1614-0075347

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08
COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '0'	System	31 Aug 2020 16:17:24
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:24:12

US3142013
Folder: Covid-19 Assessment 19 Aug 2020
Form: Generate Next COVID-19 Assessment
Generated On: 11 Aug 2021 21:57:08
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:02:19
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:14:27
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	04 Nov 2020 19:14:10
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:17:31

US3142013
Folder: Covid-19 Assessment 24 Aug 2020
Form: Generate Next COVID-19 Assessment
Generated On: 11 Aug 2021 21:57:08
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:45
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 02:12:09
DataPoint inactivated with code reason code Data not required.		28 Oct 2020 23:15:14
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:32:26

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 21:57:08
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:51:57
Data hard unlocked.		28 Apr 2021 18:35:18
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:40
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 18:43:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 18:43:04
User entered '30 Oct 2020' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:43:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 14:00:34
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 04:18:26
DataPoint activated with code reason code Data required.		04 Nov 2020 23:13:54
DataPoint inactivated with code reason code Data not required.		04 Nov 2020 23:07:16
DataPoint activated with code reason code Data required.		04 Nov 2020 23:06:53
DataPoint inactivated with code reason code Data not required.		28 Oct 2020 23:12:07
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 16:20:12
User entered empty; reason for change Data Entry Error	Shelby Pickle (b) (4) (b) (4)	28 Oct 2020 16:20:12
User entered '20 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:41:31

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 21:57:08
Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:51:57
Data hard unlocked.		28 Apr 2021 18:35:18
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:42
DataPoint activated with code reason code Data required.		13 Nov 2020 14:00:34
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 04:18:26
DataPoint activated with code reason code Data required.		04 Nov 2020 23:13:54
DataPoint inactivated with code reason code Data not required.		04 Nov 2020 23:07:16
DataPoint activated with code reason code Data required.		04 Nov 2020 23:06:53
DataPoint inactivated with code reason code Data not required.		28 Oct 2020 23:12:07
User closed query 'Data is required. Please complete.' (Site from System).		01 Sep 2020 06:08:52
Query 'Data is required. Please complete.' answered with 'Time of call unknown' (Site from System).	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:41:38
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 16:41:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:41:31

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 21:57:08
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:51:57
Data hard unlocked.		28 Apr 2021 18:35:18
Data hard locked.		27 Apr 2021 04:03:17
DataPoint activated with code reason code Data required.		13 Nov 2020 14:00:34
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 04:18:26
DataPoint activated with code reason code Data required.		04 Nov 2020 23:13:54
DataPoint inactivated with code reason code Data not required.		04 Nov 2020 23:07:16
DataPoint activated with code reason code Data required.		04 Nov 2020 23:06:53
DataPoint inactivated with code reason code Data not required.		28 Oct 2020 23:12:07
User entered empty.	System	31 Aug 2020 16:41:31

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 21:57:08
Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:51:57
Data hard unlocked.		28 Apr 2021 18:35:18
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:12:45
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 18:43:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 18:43:04
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:43:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 14:00:34
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 04:18:26
DataPoint activated with code reason code Data required.		04 Nov 2020 23:13:54
DataPoint inactivated with code reason code Data not required.		04 Nov 2020 23:07:16
DataPoint activated with code reason code Data required.		04 Nov 2020 23:06:53
DataPoint inactivated with code reason code Data not required.		28 Oct 2020 23:12:07
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 16:20:12
User entered empty; reason for change Data Entry Error	Shelby Pickle (b) (4) (b) (4)	28 Oct 2020 16:20:12
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:41:31

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US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 21:57:08
Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:51:57
Data hard unlocked.		28 Apr 2021 18:35:18
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:48
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 18:43:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 18:43:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:43:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 14:00:34
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 04:18:26
DataPoint activated with code reason code Data required.		04 Nov 2020 23:13:54
DataPoint inactivated with code reason code Data not required.		04 Nov 2020 23:07:16
DataPoint activated with code reason code Data required.		04 Nov 2020 23:06:53
DataPoint inactivated with code reason code Data not required.		28 Oct 2020 23:12:07
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 16:20:12
User entered empty; reason for change Data Entry Error	Shelby Pickle (b) (4) (b) (4)	28 Oct 2020 16:20:12
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:41:31

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 1 (Day 1)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

FDA-CBER-2022-1614-0075356

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '28 Oct 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '1'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered empty.	System	20 Nov 2020 18:45:29

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:29

FDA-CBER-2022-1614-0075377

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 2 (Day 2)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

FDA-CBER-2022-1614-0075378

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '29 Oct 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '1'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered empty.	System	20 Nov 2020 18:45:44

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

FDA-CBER-2022-1614-0075394

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:45:44

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 3 (Day 3)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '30 Oct 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '0'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

FDA-CBER-2022-1614-0075402

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '95'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered '%'	System	20 Nov 2020 18:48:39

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '97.2' F	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

FDA-CBER-2022-1614-0075407

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:48:39

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 4 (Day 4)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

FDA-CBER-2022-1614-0075422

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '31 Oct 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '1'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered empty.	System	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:49:10

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 5 (Day 5)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

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US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '01 Nov 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '0'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '90'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered '%'	System	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '98.0' F	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:52:49

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 6 (Day 6)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

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US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '02 Nov 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '1'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered empty.	System	20 Nov 2020 18:53:37

FDA-CBER-2022-1614-0075470

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

FDA-CBER-2022-1614-0075471

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

FDA-CBER-2022-1614-0075482

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:53:37

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 7 (Day 7)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

FDA-CBER-2022-1614-0075488

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '03 Nov 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '0'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '93'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered '%'	System	20 Nov 2020 18:57:42

FDA-CBER-2022-1614-0075492

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '98.1' F	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

FDA-CBER-2022-1614-0075496

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

FDA-CBER-2022-1614-0075498

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:57:42

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 8 (Day 8)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

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US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '04 Nov 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '0'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '93'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered '%'	System	20 Nov 2020 19:05:23

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '99.8' F	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

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US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

FDA-CBER-2022-1614-0075520

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

FDA-CBER-2022-1614-0075523

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:05:23

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 9 (Day 9)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

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US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '05 Nov 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '0'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '94'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered '%'	System	20 Nov 2020 19:07:00

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '99.3' F	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

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US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:07:00

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 10 (Day 10)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

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US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'Please provide corresponding SD for this visit' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 21:18:02
DataPoint Verified.		01 Mar 2021 21:17:52
Query 'Please provide corresponding SD for this visit' answered with 'Filed at this time.' (Site from CRA).	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:23:35
User opened query 'Please provide corresponding SD for this visit' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 03:56:21
DataPoint Un-verified.		24 Nov 2020 03:54:45
DataPoint Verified.		24 Nov 2020 00:58:59
User entered '06 Nov 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:17:52
DataPoint Un-verified.		24 Nov 2020 03:54:49
DataPoint Verified.		24 Nov 2020 00:58:59
User entered '0'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

FDA-CBER-2022-1614-0075556

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:17:52
DataPoint Un-verified.		24 Nov 2020 03:54:47
DataPoint Verified.		24 Nov 2020 00:58:59
User entered '93'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

FDA-CBER-2022-1614-0075557

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered '%'	System	20 Nov 2020 19:11:17

FDA-CBER-2022-1614-0075558

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:17:52
DataPoint Un-verified.		24 Nov 2020 03:54:51
DataPoint Verified.		24 Nov 2020 00:58:59
User entered '98.9' F	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

FDA-CBER-2022-1614-0075559

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:17:52
DataPoint Un-verified.		24 Nov 2020 03:54:53
DataPoint Verified.		24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

FDA-CBER-2022-1614-0075560

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:17:52
DataPoint Un-verified.		24 Nov 2020 03:54:57
DataPoint Verified.		24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

FDA-CBER-2022-1614-0075561

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:17:52
DataPoint Un-verified.		24 Nov 2020 03:54:59
DataPoint Verified.		24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:17:52
DataPoint Un-verified.		24 Nov 2020 03:55:00
DataPoint Verified.		24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:17:52
DataPoint Un-verified.		24 Nov 2020 03:55:03
DataPoint Verified.		24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

FDA-CBER-2022-1614-0075564

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:17:52
DataPoint Un-verified.		24 Nov 2020 03:55:04
DataPoint Verified.		24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

FDA-CBER-2022-1614-0075565

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:17:52
DataPoint Un-verified.		24 Nov 2020 03:55:06
DataPoint Verified.		24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:17:52
DataPoint Un-verified.		24 Nov 2020 03:55:07
DataPoint Verified.		24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:17:52
DataPoint Un-verified.		24 Nov 2020 03:55:09
DataPoint Verified.		24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:17:52
DataPoint Un-verified.		24 Nov 2020 03:55:11
DataPoint Verified.		24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:17:52
DataPoint Un-verified.		24 Nov 2020 03:55:13
DataPoint Verified.		24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

FDA-CBER-2022-1614-0075570

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:17:52
DataPoint Un-verified.		24 Nov 2020 03:55:17
DataPoint Verified.		24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:17:52
DataPoint Un-verified.		24 Nov 2020 03:55:19
DataPoint Verified.		24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

FDA-CBER-2022-1614-0075572

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:17:52
DataPoint Un-verified.		24 Nov 2020 03:55:21
DataPoint Verified.		24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

FDA-CBER-2022-1614-0075573

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:17:52
DataPoint Un-verified.		24 Nov 2020 03:55:23
DataPoint Verified.		24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:17:52
DataPoint Un-verified.		24 Nov 2020 03:55:25
DataPoint Verified.		24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:11:17

FDA-CBER-2022-1614-0075575

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 11 (Day 11)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

FDA-CBER-2022-1614-0075576

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '07 Nov 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '1'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered empty.	System	20 Nov 2020 19:14:14

FDA-CBER-2022-1614-0075580

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:14:14

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 12 (Day 12)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

FDA-CBER-2022-1614-0075598

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '08 Nov 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '1'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered empty.	System	20 Nov 2020 19:15:28

FDA-CBER-2022-1614-0075602

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 13 (Day 13)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

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US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '09 Nov 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '1'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered empty.	System	20 Nov 2020 19:15:43

FDA-CBER-2022-1614-0075624

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

FDA-CBER-2022-1614-0075636

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:15:43

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 14 (Day 14)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

FDA-CBER-2022-1614-0075642

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '10 Nov 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '0'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '97'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

FDA-CBER-2022-1614-0075645

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered '%'	System	20 Nov 2020 19:19:36

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '98.8' F	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

FDA-CBER-2022-1614-0075649

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

FDA-CBER-2022-1614-0075655

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:19:36

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 15 (Day 15)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '11 Nov 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '0'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '97'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered '%'	System	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '98.7' F	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'Please verify if this should be moderate as per source.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 21:38:21
DataPoint Verified.		01 Mar 2021 21:17:52
Query 'Please verify if this should be moderate as per source.' answered with 'Loss of smell only is moderate, this is why it is circled. No loss of taste.' (Site from CRA).	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:24:23
User opened query 'Please verify if this should be moderate as per source.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 04:02:07
DataPoint Un-verified.		24 Nov 2020 04:01:11
DataPoint Verified.		24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:23:28

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 16 (Day 16)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

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US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '12 Nov 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '0'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '96'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered '%'	System	20 Nov 2020 19:25:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '99.0' F	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

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US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:25:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 17 (Day 17)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

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US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '13 Nov 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '1'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered empty.	System	20 Nov 2020 19:29:12

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

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US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:12

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 18 (Day 18)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

FDA-CBER-2022-1614-0075730

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '14 Nov 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '1'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered empty.	System	20 Nov 2020 19:29:27

FDA-CBER-2022-1614-0075734

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

FDA-CBER-2022-1614-0075746

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:29:27

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 19 (Day 19)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

FDA-CBER-2022-1614-0075752

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '15 Nov 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '1'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered empty.	System	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:30:22

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 20 (Day 20)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

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US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '16 Nov 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '1'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered empty.	System	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:32:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 21 (Day 21)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

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US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '17 Nov 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '0'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '96'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered '%'	System	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '97.8' F	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:35:50

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Day 24 (Day 24)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

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US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '20 Nov 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '0'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '97'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User entered '%'	System	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered '98.2' F	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:57:08
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:08
Data hard unlocked.		28 Apr 2021 18:35:26
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:58:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:36:47

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08
Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:16
Data hard unlocked.		28 Apr 2021 18:35:41
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:57:40
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 18:43:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 18:43:32
DataPoint Un-verified.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:43:32
User entered '30 Oct 2020' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:43:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 14:00:46
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 04:18:36
DataPoint Verified.		05 Nov 2020 04:18:31
DataPoint activated with code reason code Data required.		04 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.		28 Oct 2020 23:12:24
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 16:20:39
User entered empty; reason for change Data Entry Error	Shelby Pickle (b) (4) (b) (4)	28 Oct 2020 16:20:39
User entered '20 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:45:04

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08
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 13:52:16
Data hard unlocked.		28 Apr 2021 18:35:41
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:57:48
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 18:43:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 18:43:32
DataPoint Un-verified.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:43:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:43:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 14:00:46
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 04:18:36
DataPoint Verified.		05 Nov 2020 04:18:31
DataPoint activated with code reason code Data required.		04 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.		28 Oct 2020 23:12:24
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 16:20:39
User entered empty; reason for change Data Entry Error	Shelby Pickle (b) (4) (b) (4)	28 Oct 2020 16:20:39
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:45:04

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08
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 13:52:16
Data hard unlocked.		28 Apr 2021 18:35:41
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:43
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).		23 Nov 2020 11:38:02
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 'Information is correct' (Site from System).	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:43:40
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 Nov 2020 18:43:32
DataPoint Un-verified.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:43:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:43:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 14:00:46
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 04:18:36
DataPoint Verified.		05 Nov 2020 04:18:31
DataPoint activated with code reason code Data required.		04 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.		28 Oct 2020 23:12:24
User closed query 'Data is required. Please complete.' (Site from System).		30 Sep 2020 15:21:28
Query 'Data is required. Please complete.' answered with 'test not preformed ' (Site from System).	Meghan York (b) (4) (b) (4)	29 Sep 2020 17:24:59
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 16:45:04

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US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered empty.	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:45:04

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08
Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:16
Data hard unlocked.		28 Apr 2021 18:35:41
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:45
DataPoint Un-verified.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:43:32
User entered '30 Oct 2020' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:43:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 14:00:46
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 04:18:36
DataPoint Verified.		05 Nov 2020 04:18:31
DataPoint activated with code reason code Data required.		04 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.		28 Oct 2020 23:12:24
User closed query 'Data is required. Please complete.' (Site from System).		30 Sep 2020 15:21:30
Query 'Data is required. Please complete.' answered with 'test not preformed ' (Site from System).	Meghan York (b) (4) (b) (4)	29 Sep 2020 17:25:08
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 16:45:04
User entered empty.	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:45:04

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08
Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:16
Data hard unlocked.		28 Apr 2021 18:35:41
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		20 Apr 2021 23:05:23
User closed query 'Lab results could not be located in the SD.' (Site from CRA).		20 Apr 2021 23:05:04
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
Query 'Lab results could not be located in the SD.' answered with 'Results are now filed in the 30 Oct 2020 visit' (Site from CRA).	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 18:26:07
User opened query 'Lab results could not be located in the SD.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 17:04:58
DataPoint Un-verified.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:43:32
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:43:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 14:00:46
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 04:18:36
DataPoint Verified.		05 Nov 2020 04:18:31
DataPoint activated with code reason code Data required.		04 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.		28 Oct 2020 23:12:24
User closed query 'Data is required. Please complete.' (Site from System).		30 Sep 2020 15:21:33
Query 'Data is required. Please complete.' answered with 'test not preformed ' (Site from System).	Meghan York (b) (4) (b) (4)	29 Sep 2020 17:25:17
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 16:45:04
User entered empty.	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:45:04

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08
Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:16
Data hard unlocked.		28 Apr 2021 18:35:41
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 14:00:46
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 04:18:36
DataPoint Verified.		05 Nov 2020 04:18:31
DataPoint activated with code reason code Data required.		04 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.		28 Oct 2020 23:12:24
User entered empty.	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:45:04

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08
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 13:52:16
Data hard unlocked.		28 Apr 2021 18:35:41
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:05:16
DataPoint Un-verified.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:43:32
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 18:43:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 14:00:46
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 04:18:36
DataPoint Verified.		05 Nov 2020 04:18:31
DataPoint activated with code reason code Data required.		04 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.		28 Oct 2020 23:12:24
User closed query 'Data is required. Please complete.' (Site from System).		30 Sep 2020 15:21:35
Query 'Data is required. Please complete.' answered with 'test not preformed ' (Site from System).	Meghan York (b) (4) (b) (4)	29 Sep 2020 17:25:27
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 16:45:04
User entered empty.	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:45:04

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08
Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:16
Data hard unlocked.		28 Apr 2021 18:35:41
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 14:00:46
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 04:18:36
DataPoint Verified.		05 Nov 2020 04:18:31
DataPoint activated with code reason code Data required.		04 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.		28 Oct 2020 23:12:24
User entered empty.	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:45:04

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08
CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:16
Data hard unlocked.		28 Apr 2021 18:35:41
Data hard locked.		27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 14:00:46
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 04:18:36
DataPoint Verified.		05 Nov 2020 04:18:31
DataPoint activated with code reason code Data required.		04 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.		28 Oct 2020 23:12:24
User entered empty.	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:45:04

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:57:08
COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:16
Data hard unlocked.		28 Apr 2021 18:35:41
Data hard locked.		27 Apr 2021 04:03:17
User entered '1'	System	20 Nov 2020 18:43:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 14:00:46
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 04:18:36
DataPoint activated with code reason code Data required.		04 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.		28 Oct 2020 23:12:24

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Respiratory Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Did the subject have Heart Rate ≥ 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Heart Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
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)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '01 Nov 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '04 Nov 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '90'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
PaO2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
High-Flow Oxygen?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Non-Invasive Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Mechanical Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
ECMO?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Evidence of Shock Requires Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

FDA-CBER-2022-1614-0075886

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Acute Renal Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Hepatic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Neurologic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'Per CDM: please provide a response for 'Neurological Dysfunction'.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 19:19:37
Query 'Per CDM: please provide a response for 'Neurological Dysfunction'.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	04 Jan 2021 16:49:35
User entered 'No (N)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	04 Jan 2021 16:49:27
User opened query 'Per CDM: please provide a response for 'Neurological Dysfunction'.' (Site from DM).	(b) (4), (b) (6)	03 Jan 2021 06:13:45
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Clinical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Radiographical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Admission to an intensive care unit due to SARS-CoV-2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:57:08
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:26
Data hard unlocked.		28 Apr 2021 18:35:50
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:14:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:44:25

US3142013
Folder: Covid-19 Assessment 30 Oct 2020
Form: Generate Next COVID-19 Assessment
Generated On: 11 Aug 2021 21:57:08
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:34
Data hard unlocked.		28 Apr 2021 18:35:57
Data hard locked.		27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:02:51
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 21:30:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 21:30:18
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	23 Nov 2020 21:30:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 14:00:57
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 04:18:51
DataPoint activated with code reason code Data required.		04 Nov 2020 23:14:26
DataPoint inactivated with code reason code Data not required.		28 Oct 2020 23:12:34
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 16:21:26
User entered empty; reason for change Data Entry Error	Shelby Pickle (b) (4) (b) (4)	28 Oct 2020 16:21:26
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	31 Aug 2020 16:21:16

FDA-CBER-2022-1614-0075902

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 21:57:08
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Day 3 (Day 3)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 21:57:08
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:13:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'NA (COVID-19 Negative) (NA)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 21:57:08
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:13:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

FDA-CBER-2022-1614-0075905

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 21:57:08
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Day 5 (Day 5)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

FDA-CBER-2022-1614-0075906

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 21:57:08
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:13:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'NA (COVID-19 Negative) (NA)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 21:57:08
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:13:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

FDA-CBER-2022-1614-0075908

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 21:57:08
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Day 7 (Day 7)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

FDA-CBER-2022-1614-0075909

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 21:57:08
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:13:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'NA (COVID-19 Negative) (NA)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 21:57:08
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:13:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

FDA-CBER-2022-1614-0075911

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 21:57:08
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Day 9 (Day 9)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

FDA-CBER-2022-1614-0075912

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 21:57:08
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:13:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'NA (COVID-19 Negative) (NA)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 21:57:08
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:13:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

FDA-CBER-2022-1614-0075914

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 21:57:08
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Day 14 (Day 14)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

FDA-CBER-2022-1614-0075915

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 21:57:08
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:13:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'NA (COVID-19 Negative) (NA)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 21:57:08
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:13:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

FDA-CBER-2022-1614-0075917

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 21:57:08
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Day 21 (Day 21)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

FDA-CBER-2022-1614-0075918

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 21:57:08
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:13:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'NA (COVID-19 Negative) (NA)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 21:57:08
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:13:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

FDA-CBER-2022-1614-0075920

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 21:57:08
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Day 28 (Day 28)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 21:57:08
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:13:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'NA (COVID-19 Negative) (NA)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

US3142013
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 21:57:08
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:13:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:21:30

FDA-CBER-2022-1614-0075923

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 21:57:08
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Day 3 (Day 3)'	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

FDA-CBER-2022-1614-0075924

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 21:57:08
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:08:48
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

FDA-CBER-2022-1614-0075925

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 21:57:08
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:08:48
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

FDA-CBER-2022-1614-0075926

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 21:57:08
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Day 5 (Day 5)'	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

FDA-CBER-2022-1614-0075927

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 21:57:08
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:08:48
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

FDA-CBER-2022-1614-0075928

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 21:57:08
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:08:48
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 21:57:08
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Day 7 (Day 7)'	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 21:57:08
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:08:48
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

FDA-CBER-2022-1614-0075931

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 21:57:08
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:08:48
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 21:57:08
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Day 9 (Day 9)'	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 21:57:08
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:08:48
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

FDA-CBER-2022-1614-0075934

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 21:57:08
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:08:48
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

FDA-CBER-2022-1614-0075935

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 21:57:08
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Day 14 (Day 14)'	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 21:57:08
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:08:48
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

FDA-CBER-2022-1614-0075937

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 21:57:08
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:08:48
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 21:57:08
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Day 21 (Day 21)'	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 21:57:08
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:08:48
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

FDA-CBER-2022-1614-0075940

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 21:57:08
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:08:48
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

FDA-CBER-2022-1614-0075941

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 21:57:08
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User accepted default value 'Day 28 (Day 28)'	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 21:57:08
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:08:48
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

FDA-CBER-2022-1614-0075943

US3142013
Folder: Illness Visit (2)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 21:57:08
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:08:48
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:19

US3142013
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:03:41
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: It appears PPD central lab has a SARS-CoV-2 serum sample dated 19 AUG 2020 as an illness Visit Day 1, but there is no record in EDC with this date. Please reconcile and update the data else clarify.' canceled (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 09:27:15
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: It appears PPD central lab has a SARS-CoV-2 serum sample dated 19 AUG 2020 as an illness Visit Day 1, but there is no record in EDC with this date. Please reconcile and update the data else clarify.' (Site from DM).		06 Jan 2021 09:21:44
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:17:43

FDA-CBER-2022-1614-0075945

US3142013
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:03:41
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '19 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:17:43

FDA-CBER-2022-1614-0075946

US3142013
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:03:41
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:17:43

FDA-CBER-2022-1614-0075947

US3142013
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'SICKD1'	System	12 Nov 2020 23:17:43

FDA-CBER-2022-1614-0075948

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:03:53
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:18:49

FDA-CBER-2022-1614-0075949

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:03:53
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '19 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:18:49

FDA-CBER-2022-1614-0075950

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:03:53
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '13:41'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:18:49

FDA-CBER-2022-1614-0075951

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '19 Aug 2020 13:41'	System	12 Nov 2020 23:18:49

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:03:53
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '68' in	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:18:49
DataPoint set to visible.	System	12 Nov 2020 23:17:43

FDA-CBER-2022-1614-0075953

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:03:53
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered missing code ND - Not Done.	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:18:49
DataPoint set to visible.	System	12 Nov 2020 23:17:43

FDA-CBER-2022-1614-0075954

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:03:53
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '97.0' F	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:18:49

FDA-CBER-2022-1614-0075955

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:03:53
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Other (Other)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:18:49

FDA-CBER-2022-1614-0075956

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:03:53
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Temporal'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:18:49

FDA-CBER-2022-1614-0075957

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:03:53
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '96'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:18:49

FDA-CBER-2022-1614-0075958

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'bpm'	System	12 Nov 2020 23:18:49

FDA-CBER-2022-1614-0075959

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:03:53
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '15'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:18:49

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'breaths/min'	System	12 Nov 2020 23:18:49

FDA-CBER-2022-1614-0075961

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:03:53
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '132'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:18:49

FDA-CBER-2022-1614-0075962

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'mmHg'	System	12 Nov 2020 23:18:49

FDA-CBER-2022-1614-0075963

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:03:53
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '80'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:18:49

FDA-CBER-2022-1614-0075964

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'mmHg'	System	12 Nov 2020 23:18:49

FDA-CBER-2022-1614-0075965

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075966

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075967

US3142013
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:57:08
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:04:11
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:19:00

FDA-CBER-2022-1614-0075968

US3142013
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:57:08
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:04:11
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '19 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:19:00

FDA-CBER-2022-1614-0075969

US3142013
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 21:57:08
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:04:27
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Thank you for the response, as per the CCG V2 page number 14 and 16, please go Patient's main page and navigate to ADD EVENT tool on the top right corner to generate the illness folder. Please review and update the EDC as the sample dated 19 AUG 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 09:18:35
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Thank you for the response, as per the CCG V2 page number 14 and 16, please go Patient's main page and navigate to ADD EVENT tool on the top right corner to generate the illness folder. Please review and update the EDC as the sample dated 19 AUG 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you.' (Site from DM).		28 Dec 2020 07:55:35
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 19 AUG 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).		28 Dec 2020 07:55:35
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 19 AUG 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 'should site add date of collection or please clairfy exactly what site needs to change' (Site from DM).	Jill York (b) (4)	23 Dec 2020 21:11:37

FDA-CBER-2022-1614-0075970

US3142013
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 21:57:08
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 19 AUG 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)	03 Dec 2020 10:36:37
User entered 'NA (COVID-19 Negative) (NA)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:19:10

US3142013
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 21:57:08
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:04:27
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Please considering updating this field with date of collection, Thank you' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 14:41:39
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Please considering updating this field with date of collection, Thank you' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	19 Jan 2021 17:55:30
User entered '19 Aug 2020' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	19 Jan 2021 17:55:23
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Please considering updating this field with date of collection, Thank you' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 09:28:16
User entered empty.	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:19:10

US3142013
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:07:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'Per ETRTR: Please complete data entry within Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 20:58:00
Query 'Per ETRTR: Please complete data entry within Saliva Collection page, thanks.' answered with 'done' (Site from CRA).	Jill York (b) (4)	24 Mar 2021 13:57:46
User opened query 'Per ETRTR: Please complete data entry within Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:37:43
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:51:35

US3142013
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:07:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '30 Oct 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:51:35

FDA-CBER-2022-1614-0075974

US3142013
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:07:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:51:35

FDA-CBER-2022-1614-0075975

US3142013
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'SICKD1'	System	20 Nov 2020 19:51:35

FDA-CBER-2022-1614-0075976

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:07:28
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:52:13

FDA-CBER-2022-1614-0075977

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:07:28
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '30 Oct 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:52:13

FDA-CBER-2022-1614-0075978

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:07:28
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '09:08'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:52:13

FDA-CBER-2022-1614-0075979

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '30 Oct 2020 09:08'	System	20 Nov 2020 19:52:13

FDA-CBER-2022-1614-0075980

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:07:28
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered missing code ND - Not Done.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:52:13
DataPoint set to visible.	System	20 Nov 2020 19:51:35

FDA-CBER-2022-1614-0075981

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:07:28
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered missing code ND - Not Done.	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:52:13
DataPoint set to visible.	System	20 Nov 2020 19:51:35

FDA-CBER-2022-1614-0075982

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:07:28
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '97.2' F	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:52:13

FDA-CBER-2022-1614-0075983

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:07:28
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Other (Other)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:52:13

FDA-CBER-2022-1614-0075984

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:07:28
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Temporal'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:52:13

FDA-CBER-2022-1614-0075985

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:07:28
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '94'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:52:13

FDA-CBER-2022-1614-0075986

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'bpm'	System	20 Nov 2020 19:52:13

FDA-CBER-2022-1614-0075987

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:07:28
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '14'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:52:13

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'breaths/min'	System	20 Nov 2020 19:52:13

FDA-CBER-2022-1614-0075989

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:07:28
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '130'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:52:13

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'mmHg'	System	20 Nov 2020 19:52:13

FDA-CBER-2022-1614-0075991

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:07:28
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '81'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:52:13

FDA-CBER-2022-1614-0075992

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'mmHg'	System	20 Nov 2020 19:52:13

FDA-CBER-2022-1614-0075993

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075994

US3142013
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0075995

US3142013
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:57:08
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:08:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:52:22

FDA-CBER-2022-1614-0075996

US3142013
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:57:08
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:08:01
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '30 Oct 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:52:22

US3142013
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 21:57:08
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:08:10
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:52:31

US3142013
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 21:57:08
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:08:10
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '30 Oct 2020'	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:52:31

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:12:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:20:33

FDA-CBER-2022-1614-0076000

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:12:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:20:33

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:12:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:20:33

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:57:08
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered 'SICKD28'	System	01 Mar 2021 18:20:33

FDA-CBER-2022-1614-0076003

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:11:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:20:52

FDA-CBER-2022-1614-0076004

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:11:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:20:52

FDA-CBER-2022-1614-0076005

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:11:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:20:52

FDA-CBER-2022-1614-0076006

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	01 Mar 2021 18:20:52

FDA-CBER-2022-1614-0076007

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:11:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:20:52

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:11:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:20:52

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:11:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:20:52

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:11:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:20:52

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	01 Mar 2021 18:20:52

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:11:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:20:52

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	01 Mar 2021 18:20:52

FDA-CBER-2022-1614-0076014

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:11:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:20:52

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	01 Mar 2021 18:20:52

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:11:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:20:52

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	01 Mar 2021 18:20:52

FDA-CBER-2022-1614-0076018

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0076019

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:57:08
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0076020

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:57:08
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:12:43
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:20:58

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US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:57:08
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:12:43
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:20:58

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 21:57:08
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:12:52
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:04

US3142013
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 21:57:08
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:12:52
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	01 Mar 2021 18:21:04

US3142013
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 11 Aug 2021 21:57:08
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.		18 Apr 2021 18:54:52
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 4; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).		30 Mar 2021 04:28:35
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 10). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).		30 Mar 2021 04:28:33
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 10). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'AE now entered ' (Site from DM).	Jill York (b) (4)	26 Mar 2021 01:03:39
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 4; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'AE now entered ' (Site from DM).	Jill York (b) (4)	26 Mar 2021 01:03:15
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 4; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 04:24:16

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US3142013
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 11 Aug 2021 21:57:08
Did the participant experience any adverse events?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 10). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 04:24:09
DataPoint Verified.		02 Feb 2021 17:29:21
User closed query 'Per CDM: Please update the AE form accordingly. ' (Site from DM).		17 Nov 2020 08:15:41
Query 'Per CDM: Please update the AE form accordingly. ' answered with 'Will provide' (Site from DM).	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:09:32
User opened query 'Per CDM: Please update the AE form accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:38:13
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	27 Oct 2020 20:47:11

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:46:24
User entered 'USA-US064-2020-mRNA-1273-P301000004'		13 Nov 2020 21:46:14
User entered 'New'		13 Nov 2020 21:46:14

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US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
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)	12 Nov 2020 23:12:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:12:41
Data point term sent to Coder	System	12 Nov 2020 23:11:19
User entered 'COVID-19'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'Per CDM, Per Sponsor review: Covid-19 AE present but Was this a medically-attended AE? Is marked NO. Please review and reconcile. Else clarify ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 17:23:47
Query 'Per CDM, Per Sponsor review: Covid-19 AE present but Was this a medically-attended AE? Is marked NO. Please review and reconcile. Else clarify ' answered with 'corrected' (Site from DM).	Jami Wagner (b) (4) (b) (4)	12 Apr 2021 19:28:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Jami Wagner (b) (4) (b) (4)	12 Apr 2021 19:27:34
User opened query 'Per CDM, Per Sponsor review: Covid-19 AE present but Was this a medically-attended AE? Is marked NO. Please review and reconcile. Else clarify ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 08:54:49
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

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US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

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US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'PV Query: Symptoms and testing reported were in Aug 2020, however the event onset date was in 28 Oct 2020, please clarify.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 01:54:35
Query 'PV Query: Symptoms and testing reported were in Aug 2020, however the event onset date was in 28 Oct 2020, please clarify.' answered with '2 separate sicknesses.' (Site from Safety).	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:47:21
User opened query 'PV Query: Symptoms and testing reported were in Aug 2020, however the event onset date was in 28 Oct 2020, please clarify.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 15:09:10
User entered '28 Oct 2020'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:47:51
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 01:54:39
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Added' (Site from Safety).	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:47:58
User entered '17 Nov 2020' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:47:51
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 15:03:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

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US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:40
User entered 'Grade 1/Mild (Grade 1/Mild)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

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US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

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US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

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US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

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US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Not Related (NOT RELATED)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Not Related (NOT RELATED)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'PV Query: As the event occurred after the second dose of the study drug, please update the action taken with the study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 01:54:45
Query 'PV Query: As the event occurred after the second dose of the study drug, please update the action taken with the study drug from none to not applicable.' answered with 'Updated' (Site from Safety).	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:48:17
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:48:12
User opened query 'PV Query: As the event occurred after the second dose of the study drug, please update the action taken with the study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 15:07:07
User entered 'None (NONE)'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '1'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

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US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 01:54:49
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Updated' (Site from Safety).	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:48:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:47:51
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 15:08:08
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 23:11:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 23:11:19
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:19
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 23:11:03
User entered empty.	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'PV Query: Please provide the subject's signs/symptoms associated with COVID-19 infection in Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 16:53:56
Query 'PV Query: Please provide the subject's signs/symptoms associated with COVID-19 infection in Oct 2020.' answered with 'narrative entered per query' (Site from Safety).	Jami Wagner (b) (4) (b) (4)	30 Mar 2021 18:39:57
User entered 'Subject presented with the following mild symptoms: cough, shortness of breath, congestion, and chills. Subject also reported the following moderate symptoms: Fatigue, muscle/body aches, headache, sore throat, diarrhea' reason for change: Data Entry Error	Jami Wagner (b) (4) (b) (4)	30 Mar 2021 18:39:06
User closed query 'PV Query: Please provide the results of COVID-19 positive testing, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 01:54:57
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		30 Nov 2020 01:54:54
Query 'PV Query: Please provide the results of COVID-19 positive testing, including date of collection and type of testing. If not done, please state so.' answered with 'Provided' (Site from Safety).	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:48:42

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'No treatment necessary' (Site from Safety).	Shelby Pickle (b) (4) (b) (4)	20 Nov 2020 19:48:36
User opened query 'PV Query: Please provide the subject's signs/symptoms associated with COVID-19 infection in Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 15:09:37
Query 'PV Query: Symptoms and testing reported were in Aug 2020, however the event onset date was in 28 Oct 2020, please clarify.' canceled (Site from Safety).		19 Nov 2020 15:08:56
User opened query 'PV Query: Symptoms and testing reported were in Aug 2020, however the event onset date was in 28 Oct 2020, please clarify.' (Site from Safety).		19 Nov 2020 15:08:48
User opened query 'PV Query: Please provide the results of COVID-19 positive testing, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		19 Nov 2020 15:07:29
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		19 Nov 2020 15:06:36
User entered empty.	Shelby Pickle (b) (4) (b) (4)	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '0'	System	12 Nov 2020 23:11:03

FDA-CBER-2022-1614-0076061

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1'	System	12 Apr 2021 19:27:34
User entered '0'	System	12 Nov 2020 23:11:03

US3142013
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:57:08
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0076064

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Mar 2021 10:24:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Mar 2021 10:24:42
Data point term sent to Coder	System	26 Mar 2021 00:58:14
User entered 'fatigue persisting past 7 days'	Jill York (b) (4)	26 Mar 2021 00:57:19

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Jill York (b) (4)	26 Mar 2021 00:57:19

FDA-CBER-2022-1614-0076066

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Jill York (b) (4)	26 Mar 2021 00:57:19

FDA-CBER-2022-1614-0076067

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Jill York (b) (4)	26 Mar 2021 00:57:19

FDA-CBER-2022-1614-0076068

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
User entered '31 Jul 2020'	(b) (4) Jill York (b) (4)	26 Mar 2021 00:57:19

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 08:57:53
Query 'Data is required. Please provide.' answered with 'time unknown' (Site from System).	Jill York (b) (4)	26 Mar 2021 01:01:53
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Mar 2021 00:57:19
User entered empty.	Jill York (b) (4)	26 Mar 2021 00:57:19

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	26 Mar 2021 00:57:19

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Jill York (b) (4)	26 Mar 2021 00:57:19

FDA-CBER-2022-1614-0076072

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
User entered '8 Aug 2020'	(b) (4) Jill York (b) (4)	26 Mar 2021 00:57:19

FDA-CBER-2022-1614-0076073

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 08:57:55
Query 'Data is required. Please provide.' answered with 'time unknown' (Site from System).	Jill York (b) (4)	26 Mar 2021 01:02:02
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Mar 2021 00:57:19
User entered empty.	Jill York (b) (4)	26 Mar 2021 00:57:19

FDA-CBER-2022-1614-0076074

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	26 Mar 2021 00:57:19

FDA-CBER-2022-1614-0076075

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Jill York (b) (4)	26 Mar 2021 00:57:19

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Jill York (b) (4)	26 Mar 2021 00:57:19

FDA-CBER-2022-1614-0076077

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Jill York (b) (4)	26 Mar 2021 00:57:19

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Jill York (b) (4)	26 Mar 2021 00:57:19

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Jill York (b) (4)	26 Mar 2021 00:57:19

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Jill York (b) (4)	26 Mar 2021 00:57:19

FDA-CBER-2022-1614-0076081

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Jill York (b) (4)	26 Mar 2021 00:57:19

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Jill York (b) (4)	26 Mar 2021 00:57:19

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Jill York (b) (4)	26 Mar 2021 00:57:19

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Jill York (b) (4) (b) (4)	26 Mar 2021 00:57:19

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Jill York (b) (4)	26 Mar 2021 00:57:19

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
User entered '0'	(b) (4) Jill York (b) (4)	26 Mar 2021 00:57:19

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US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
User entered 'Related (RELATED)'	(b) (4) Jill York (b) (4)	26 Mar 2021 00:57:19

FDA-CBER-2022-1614-0076088

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
User entered 'Not Related (NOT RELATED)'	(b) (4) Jill York (b) (4)	26 Mar 2021 00:57:19

FDA-CBER-2022-1614-0076089

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
User entered 'None (NONE)'	(b) (4) Jill York (b) (4)	26 Mar 2021 00:57:19

FDA-CBER-2022-1614-0076090

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '1'	Jill York (b) (4)	26 Mar 2021 00:57:19

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Jill York (b) (4)	26 Mar 2021 00:57:19

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Jill York (b) (4)	26 Mar 2021 00:57:19

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jill York (b) (4)	26 Mar 2021 00:57:19

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Jill York (b) (4)	26 Mar 2021 00:57:19

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Jill York (b) (4)	26 Mar 2021 00:57:19

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US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '0'	System	26 Mar 2021 00:57:19

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '0'	System	26 Mar 2021 00:57:19

US3142013
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 21:57:08
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
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)	26 Mar 2021 10:26:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Mar 2021 10:26:42
Data point term sent to Coder	System	26 Mar 2021 01:02:17
User entered 'Headache persisting past 7 days'	Jill York (b) (4)	26 Mar 2021 01:01:29

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Jill York (b) (4)	26 Mar 2021 01:01:29

FDA-CBER-2022-1614-0076102

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Yes (Y)'	Jill York (b) (4)	26 Mar 2021 01:01:29

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Jill York (b) (4)	26 Mar 2021 01:01:29

FDA-CBER-2022-1614-0076104

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 02AUG2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:23:58
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 02AUG2020. Please review if this should be reconciled. Else, provide clarification on dates. ' answered with 'done' (Site from DM).	Jami Wagner (b) (4) (b) (4)	12 Apr 2021 19:50:30
User entered '2 Aug 2020' reason for change: Data Entry Error	Jami Wagner (b) (4) (b) (4)	12 Apr 2021 19:49:37
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 02AUG2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 04:01:30
User entered '1 Aug 2020'	Jill York (b) (4)	26 Mar 2021 01:01:29

FDA-CBER-2022-1614-0076105

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Jill York (b) (4)	26 Mar 2021 01:01:29

FDA-CBER-2022-1614-0076106

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	26 Mar 2021 01:01:29

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Jill York (b) (4)	26 Mar 2021 01:01:29

FDA-CBER-2022-1614-0076108

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
User entered '7 Aug 2020'	(b) (4) Jill York (b) (4)	26 Mar 2021 01:01:29

FDA-CBER-2022-1614-0076109

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Jill York (b) (4)	26 Mar 2021 01:01:29

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	26 Mar 2021 01:01:29

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Jill York (b) (4)	26 Mar 2021 01:01:29

FDA-CBER-2022-1614-0076112

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	(b) (4) Jill York (b) (4)	26 Mar 2021 01:01:29

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Jill York (b) (4)	26 Mar 2021 01:01:29

FDA-CBER-2022-1614-0076114

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Jill York (b) (4)	26 Mar 2021 01:01:29

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Jill York (b) (4)	26 Mar 2021 01:01:29

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Jill York (b) (4)	26 Mar 2021 01:01:29

FDA-CBER-2022-1614-0076117

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Jill York (b) (4)	26 Mar 2021 01:01:29

FDA-CBER-2022-1614-0076118

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Jill York (b) (4)	26 Mar 2021 01:01:29

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Jill York (b) (4)	26 Mar 2021 01:01:29

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Jill York (b) (4)	26 Mar 2021 01:01:29

FDA-CBER-2022-1614-0076121

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Jill York (b) (4)	26 Mar 2021 01:01:29

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Jill York (b) (4)	26 Mar 2021 01:01:29

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Related (RELATED)'	Jill York (b) (4)	26 Mar 2021 01:01:29

FDA-CBER-2022-1614-0076124

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
User entered 'Not Related (NOT RELATED)'	(b) (4) Jill York (b) (4)	26 Mar 2021 01:01:29

FDA-CBER-2022-1614-0076125

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
User entered 'None (NONE)'	Jill York (b) (4) (b) (4)	26 Mar 2021 01:01:29

FDA-CBER-2022-1614-0076126

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '1'	Jill York (b) (4)	26 Mar 2021 01:01:29

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Jill York (b) (4)	26 Mar 2021 01:01:29

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '0'	Jill York (b) (4)	26 Mar 2021 01:01:29

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jill York (b) (4)	26 Mar 2021 01:01:29

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Jill York (b) (4)	26 Mar 2021 01:01:29

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Jill York (b) (4)	26 Mar 2021 01:01:29

FDA-CBER-2022-1614-0076132

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '0'	System	26 Mar 2021 01:01:29

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '0'	System	26 Mar 2021 01:01:29

US3142013
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 21:57:08
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 11 Aug 2021 21:57:08
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:29:46
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).		19 Nov 2020 06:43:56
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'Subject was contacted. Medication is now listed under ConMed page. ' (Site from DM).	Meghan York (b) (4) (b) (4)	17 Nov 2020 19:24:47
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 16:44:25
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:58:19

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:57:08
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:30:34
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 02:00:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 02:00:04
Data point term sent to Coder	System	04 Aug 2020 01:59:38
User entered 'Symbicort'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:10

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:57:08
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:30:36
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:10

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:57:08
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:30:43
User entered 'Asthma'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:10

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:57:08
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:30:39
User entered '80/4.5'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:10

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:57:08
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:30:41
User entered 'Other (OTHER)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:10

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:57:08
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:30:48
User entered 'mcg'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:10

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:57:08
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:30:50
User entered 'as needed (PRN)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:10

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:57:08
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:30:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:10

FDA-CBER-2022-1614-0076144

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:57:08
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:30:54
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:10

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:57:08
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:30:56
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:10

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:57:08
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:05
User closed 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).		04 Aug 2020 14:49:54
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.' answered with 'Per IM all medications reported' (Site from System).	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:21
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	04 Aug 2020 01:59:10
User entered 'UN UNK 2018'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:10

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:57:08
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:08
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:10

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:57:08
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:14
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:10

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:57:08
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:17
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:10

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:57:08
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:21
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:10

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:57:08
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:59:10

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:57:08
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:59:10

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:57:08
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 01:59:10

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:57:08
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 02:02:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 02:02:10
Data point term sent to Coder	System	04 Aug 2020 02:00:38
User entered 'Singulair'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:53

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:57:08
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:53

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:57:08
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'Asthma'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:53

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:57:08
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered '10'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:53

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:57:08
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'mg (mg)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:53

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:57:08
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:53

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:57:08
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'once daily (QD)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:53

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:57:08
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:53

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:57:08
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'Oral (ORAL)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:53

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:57:08
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:53

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:57:08
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User closed 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).		04 Aug 2020 14:50:08
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.' answered with 'Per IM all medications to be reported' (Site from System).	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:00:03
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 01:59:53
User entered 'UN UNK 2018'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:53

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:57:08
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:53

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:57:08
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:53

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:57:08
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:53

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:57:08
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 01:59:53

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:57:08
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1'	System	04 Aug 2020 01:59:53

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:57:08
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1'	System	04 Aug 2020 01:59:53

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:57:08
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '804 (804)'	System	04 Aug 2020 01:59:53

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 21:57:08
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 13:54:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 13:54:10
Data point term sent to Coder	System	04 Aug 2020 02:01:39
User entered 'Zoloft'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:00:44

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US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 21:57:08
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:00:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 21:57:08
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'Post Traumatic Stress Disorder'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:00:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 21:57:08
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered '200'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:00:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 21:57:08
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'mg (mg)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:00:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 21:57:08
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:00:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 21:57:08
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'once daily (QD)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:00:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 21:57:08
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:00:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 21:57:08
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'Oral (ORAL)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:00:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 21:57:08
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:00:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 21:57:08
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User closed 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).		04 Aug 2020 14:50:33
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.' answered with 'Per IM all medications to be reported' (Site from System).	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:00:54
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	04 Aug 2020 02:00:44
User entered 'UN UNK 2019'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:00:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 21:57:08
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:00:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 21:57:08
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:00:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 21:57:08
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:00:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 21:57:08
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:00:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 21:57:08
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1'	System	04 Aug 2020 02:00:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 21:57:08
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1'	System	04 Aug 2020 02:00:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 21:57:08
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '804 (804)'	System	04 Aug 2020 02:00:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 21:57:08
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 02:02:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 02:02:10
Data point term sent to Coder	System	04 Aug 2020 02:01:39
User entered 'Hydroxyzine'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:01:37

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 21:57:08
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:01:37

FDA-CBER-2022-1614-0076192

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 21:57:08
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'Anxiety'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:01:37

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 21:57:08
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered '50'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:01:37

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 21:57:08
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'mg (mg)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:01:37

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 21:57:08
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:01:37

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 21:57:08
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'as needed (PRN)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:01:37

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 21:57:08
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:01:37

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 21:57:08
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'Oral (ORAL)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:01:37

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 21:57:08
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:01:37

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 21:57:08
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User closed 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).		04 Aug 2020 14:50:49
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.' answered with 'Per IM all medications to be reported' (Site from System).	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:01:48
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	04 Aug 2020 02:01:37
User entered 'UN UNK 2019'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:01:37

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 21:57:08
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered '0'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:01:37

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 21:57:08
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:01:37

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 21:57:08
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered empty.	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:01:37

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 21:57:08
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	04 Aug 2020 02:01:37

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 21:57:08
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 02:01:37

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 21:57:08
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 02:01:37

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 21:57:08
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered empty.	System	04 Aug 2020 02:01:37

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 21:57:08
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: NYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 22:45:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 22:45:18
Data point term sent to Coder	System	12 Apr 2021 19:41:11
User closed query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	System	12 Apr 2021 19:40:40
Query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' answered with 'done' (Site from System).	Jami Wagner (b) (4) (b) (4)	12 Apr 2021 19:40:40
DataPoint Un-verified.	Jami Wagner (b) (4) (b) (4)	12 Apr 2021 19:40:19
Coding entries removed.	Jami Wagner (b) (4) (b) (4)	12 Apr 2021 19:40:19
User entered 'NYQUIL (acetaminophen 650mg/ Dextromethorphan HBr 30mg/ Doxylamine 12.5 mg)' reason for change: Data Entry Error	Jami Wagner (b) (4) (b) (4)	12 Apr 2021 19:40:19
User opened query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	Coder Import (b) (4) (b) (4)	06 Apr 2021 14:58:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39

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US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 21:57:08
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 19:27:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 19:27:49
Data point term sent to Coder	System	17 Nov 2020 19:26:48
User entered 'Nyquil'	Meghan York (b) (4) (b) (4)	17 Nov 2020 19:26:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 21:57:08
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	17 Nov 2020 19:26:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 21:57:08
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 18:43:27
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'not considered an AE' (Site from DM).	Meghan York (b) (4) (b) (4)	28 Jan 2021 17:13:12

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 21:57:08
Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 07:10:47
User entered 'headache'	Meghan York (b) (4) (b) (4)	17 Nov 2020 19:26:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 21:57:08
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered '2'	Meghan York (b) (4) (b) (4)	17 Nov 2020 19:26:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 21:57:08
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'Other (OTHER)'	Meghan York (b) (4) (b) (4)	17 Nov 2020 19:26:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 21:57:08
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'tablespoons'	Meghan York (b) (4) (b) (4)	17 Nov 2020 19:26:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 21:57:08
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	17 Nov 2020 19:26:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 21:57:08
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered empty.	Meghan York (b) (4) (b) (4)	17 Nov 2020 19:26:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 21:57:08
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	17 Nov 2020 19:26:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 21:57:08
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered empty.	Meghan York (b) (4) (b) (4)	17 Nov 2020 19:26:44

FDA-CBER-2022-1614-0076220

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 21:57:08
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered '30 Sep 2020'	Meghan York (b) (4) (b) (4)	17 Nov 2020 19:26:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 21:57:08
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered '0'	Meghan York (b) (4) (b) (4)	17 Nov 2020 19:26:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 21:57:08
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	17 Nov 2020 19:26:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 21:57:08
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered '30 Sep 2020'	Meghan York (b) (4) (b) (4)	17 Nov 2020 19:26:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 21:57:08
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:31:39
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	17 Nov 2020 19:26:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 21:57:08
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1'	System	17 Nov 2020 19:26:44

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 21:57:08
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '1'	System	17 Nov 2020 19:26:44

FDA-CBER-2022-1614-0076227

US3142013
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 21:57:08
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '804 (804)'	System	17 Nov 2020 19:26:44

US3142013
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 11 Aug 2021 21:57:08
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	20 Oct 2020 19:18:38

US3142013
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 21:57:08
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User closed query 'Per CDM: As per CCGs, if participant was lost to follow-up, use date of last direct contact (e.g., clinic visit or phone call) with the participant. So please review and confirm the Date of study discontinuation.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 15:58:10
Query 'Per CDM: As per CCGs, if participant was lost to follow-up, use date of last direct contact (e.g., clinic visit or phone call) with the participant. So please review and confirm the Date of study discontinuation.' answered with 'now corrected ' (Site from DM).	Jill York (b) (4)	23 Mar 2021 15:18:34
User entered '26 Feb 2021' reason for change: Data Entry Error	Jill York (b) (4)	23 Mar 2021 15:17:18
User opened query 'Per CDM: As per CCGs, if participant was lost to follow-up, use date of last direct contact (e.g., clinic visit or phone call) with the participant. So please review and confirm the Date of study discontinuation.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 12:54:19
User entered '03 Mar 2021'	Shelby Pickle (b) (4) (b) (4)	09 Mar 2021 21:48:44

US3142013
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 21:57:08
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered 'Lost To Follow-up (LOST TO FOLLOW-UP)'	Shelby Pickle (b) (4) (b) (4)	09 Mar 2021 21:48:44

US3142013
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 21:57:08
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	09 Mar 2021 21:48:44

US3142013
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 21:57:08
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	09 Mar 2021 21:48:44

US3142013
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 21:57:08
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	09 Mar 2021 21:48:44

FDA-CBER-2022-1614-0076234

US3142013
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 21:57:08
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	09 Mar 2021 21:48:44

FDA-CBER-2022-1614-0076235

US3142013
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 21:57:08
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered empty.	Shelby Pickle (b) (4) (b) (4)	09 Mar 2021 21:48:44

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:20
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'USA-US064-2020-MRNA-1273-P301000004'	System	13 Nov 2020 21:46:14

FDA-CBER-2022-1614-0076237

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:22
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:28
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:25
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:30
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:31
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:28:50
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:54
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:52
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'Ripley'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:56
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'Hollister'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:28:58
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered '4190 East Woodmen Road Suite 210'	System	13 Nov 2020 21:46:14

FDA-CBER-2022-1614-0076247

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:29:04
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'Colorado Springs'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:29:06
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered '80920'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:29:10
Reviewed for Safety.		30 Nov 2020 01:47:41
User entered 'US'	System	13 Nov 2020 21:46:36

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '3'	System	31 Mar 2021 16:54:37
User entered '2'	System	30 Nov 2020 01:47:54
User entered '1'	System	13 Nov 2020 21:46:36

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:20
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'USA-US064-2020-MRNA-1273-P301000004'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:22
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:28
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:25
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:28:30
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:31
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:50
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:54
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:52
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'Ripley'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:28:56
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'Hollister'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:58
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered '4190 East Woodmen Road Suite 210'	System	13 Nov 2020 21:46:14

FDA-CBER-2022-1614-0076263

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:29:04
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'Colorado Springs'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0076265

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:29:06
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered '80920'	System	13 Nov 2020 21:46:14

FDA-CBER-2022-1614-0076266

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:29:10
Reviewed for Safety.		30 Nov 2020 01:47:41
User entered 'US'	System	13 Nov 2020 21:46:36

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '3'	System	31 Mar 2021 16:54:37
User entered '2'	System	30 Nov 2020 01:47:54
User entered '1'	System	13 Nov 2020 21:46:36

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form (1)
Generated On: 11 Aug 2021 21:57:08
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:53
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '13/Nov/2020 21:46'	System	13 Nov 2020 21:46:36

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form (1)
Generated On: 11 Aug 2021 21:57:08
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)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:53
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 01:47:41
User entered '1'		13 Nov 2020 21:46:36

FDA-CBER-2022-1614-0076270

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:20
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'USA-US064-2020-MRNA-1273-P301000004'	System	13 Nov 2020 21:46:14

FDA-CBER-2022-1614-0076271

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:22
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:28
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:25
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:30
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:31
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:28:50
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:54
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:52
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'Ripley'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:56
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'Hollister'	System	13 Nov 2020 21:46:14

FDA-CBER-2022-1614-0076280

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:58
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered '4190 East Woodmen Road Suite 210'	System	13 Nov 2020 21:46:14

FDA-CBER-2022-1614-0076281

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:29:04
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'Colorado Springs'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:29:06
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered '80920'	System	13 Nov 2020 21:46:14

FDA-CBER-2022-1614-0076284

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:29:10
Reviewed for Safety.		30 Nov 2020 01:47:41
User entered 'US'	System	13 Nov 2020 21:46:36

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '3'	System	31 Mar 2021 16:54:37
User entered '2'	System	30 Nov 2020 01:47:54
User entered '1'	System	13 Nov 2020 21:46:36

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form (2)
Generated On: 11 Aug 2021 21:57:08
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:53
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
User entered '30/Nov/2020 01:47'	(b) (4) System	30 Nov 2020 01:47:54

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form (2)
Generated On: 11 Aug 2021 21:57:08
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)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:53
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 16:54:19
User entered '1'		30 Nov 2020 01:47:54

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:20
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'USA-US064-2020-MRNA-1273-P301000004'	System	13 Nov 2020 21:46:14

FDA-CBER-2022-1614-0076289

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:22
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:28
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

FDA-CBER-2022-1614-0076291

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:25
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:30
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:31
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:50
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:54
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'No (N)'	System	13 Nov 2020 21:46:14

FDA-CBER-2022-1614-0076296

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:52
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'Ripley'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:56
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'Hollister'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:28:58
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered '4190 East Woodmen Road Suite 210'	System	13 Nov 2020 21:46:14

FDA-CBER-2022-1614-0076299

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:29:04
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered 'Colorado Springs'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17

FDA-CBER-2022-1614-0076301

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:29:06
Reviewed for Safety.		13 Nov 2020 21:46:31
User entered '80920'	System	13 Nov 2020 21:46:14

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:29:10
Reviewed for Safety.		30 Nov 2020 01:47:41
User entered 'US'	System	13 Nov 2020 21:46:36

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 11 Aug 2021 21:57:08
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
User entered '3'	System	31 Mar 2021 16:54:37
User entered '2'	System	30 Nov 2020 01:47:54
User entered '1'	System	13 Nov 2020 21:46:36

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form (3)
Generated On: 11 Aug 2021 21:57:08
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:53
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 18:54:52
User entered '31/Mar/2021 11:54'	System	31 Mar 2021 16:54:37

FDA-CBER-2022-1614-0076305

US3142013
Folder: SAE USA-US064-2020-MRNA-1273-P301000004
Form: Safety Report Form (3)
Generated On: 11 Aug 2021 21:57:08
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)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:03:17
DataPoint Verified.		22 Apr 2021 16:10:53
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 18:54:52
User entered '1'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:54:37

FDA-CBER-2022-1614-0076306