US3402382 (Prod: Meridian Clinical Research, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:29:09

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US3402382
Form: Participant Creation
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

Participant ID	US3402382

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-1767788

US3402382
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **08 Mar 2021 22:42:48**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767789

US3402382
Folder: Screening
Form: Demographics
Data signed: (b) (4) **08 Mar 2021 22:42:47**
Generated On: 09 Jun 2021 17:29:09

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	66
Age Units	YEARS
Age (Derived)	67
Sex	Female ☐ Male ■
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ■ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

FDA-CBER-2022-1614-1767790

US3402382
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **08 Mar 2021 22:42:48**
Generated On: 09 Jun 2021 17:29:09

Date of Informed Consent *(dd MMM yyyy)*	16 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐ Amendment 2 ■ Amendment 3 ☐ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ■ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ■
If Yes, previous participant number	
Enrollment Trigger	1

FDA-CBER-2022-1614-1767791

US3402382
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **08 Mar 2021 22:42:48**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767792

US3402382
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **08 Mar 2021 22:42:48**
Generated On: 09 Jun 2021 17:29:09

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-1767793

US3402382
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **08 Mar 2021 22:42:48**
Generated On: 09 Jun 2021 17:29:09

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-1767794

US3402382
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **08 Mar 2021 22:42:48**
Generated On: 09 Jun 2021 17:29:09

Condition	TORN ACL RIGHT LEG
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-1767795

US3402382
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **08 Mar 2021 22:42:48**
Generated On: 09 Jun 2021 17:29:09

Condition	HYPERLIPIDEMIA
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)	

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US3402382
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **08 Mar 2021 22:42:48**
Generated On: 09 Jun 2021 17:29:09

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-1767797

US3402382
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **08 Mar 2021 22:42:48**
Generated On: 09 Jun 2021 17:29:09

Condition	GOUT
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

US3402382
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **08 Mar 2021 22:42:48**
Generated On: 09 Jun 2021 17:29:09

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	25 AUG 2008
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)	AUG 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

US3402382
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **08 Mar 2021 22:42:48**
Generated On: 09 Jun 2021 17:29:09

Condition	BENIGN PROSTATIC HYPERTROPHY
Start date (dd MMM yyyy)	01 SEP 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)	SEP 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3402382
Folder: Screening
Form: Medical History (8)
Data signed: (b) (4) **08 Mar 2021 22:42:48**
Generated On: 09 Jun 2021 17:29:09

Condition	BILATERAL HIP OSTEOARTHRITIS
Start date (dd MMM yyyy)	25 APR 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☑ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-1767801

US3402382
Folder: Screening
Form: Medical History (9)
Data signed: (b) (4) **08 Mar 2021 22:42:48**
Generated On: 09 Jun 2021 17:29:09

Condition	ANXIETY
Start date (dd MMM yyyy)	05 NOV 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-1767802

US3402382
Folder: Screening
Form: Medical History (10)
Data signed: (b) (4) **08 Mar 2021 22:42:48**
Generated On: 09 Jun 2021 17:29:09

Condition	CONSTIPATION
Start date (dd MMM yyyy)	04 NOV 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)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-1767803

US3402382
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **08 Mar 2021 22:42:48**
Generated On: 09 Jun 2021 17:29:09

Were vital signs assessed?	Yes ☑ No ☐
Date of assessment *(dd MMM yyyy)*	16 AUG 2020
Time of assessment *(00:00-23:59)*	12:21 (24 HR)
Vital Signs Date and Time (derived)	16 AUG 2020 12:21
Height *(xxx.x)*	74 in
Weight *(xxx.x)*	282 lb
BMI *(xxx.x)*	36.28236 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)	

US3402382
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **08 Mar 2021 22:42:48**
Generated On: 09 Jun 2021 17:29:09

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

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

FDA-CBER-2022-1614-1767805

US3402382
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **08 Mar 2021 22:42:48**
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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	TOWN (b) (6)
Location and Living Circumstances Risk (check all that apply)	
No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False

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US3402382
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **08 Mar 2021 22:42:48**
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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

FDA-CBER-2022-1614-1767807

US3402382
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	16 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT1

FDA-CBER-2022-1614-1767808

US3402382
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

What was the date of randomization? *(dd MMM yyyy)*	16 AUG 2020
What was the participant's randomization number?	186501
In what Cohort was the participant enrolled?	>=18 and <65 years and not at risk ☐ >=18 and <65 years and at risk ☐ >=65 years ■

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

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

FDA-CBER-2022-1614-1767809

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-1767810

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

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)*	16 AUG 2020
Time of assessment *(00:00-23:59)*	12:21 (24 HR)
Vital Signs Date and Time (derived)	16 AUG 2020 12:21
Temperature *(xxx.x)*	36.3 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	89 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	62 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-1767811

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

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)*	16 AUG 2020
Time of assessment *(00:00-23:59)*	13:45 (24 HR)
Vital Signs Date and Time (derived)	16 AUG 2020 13:45
Temperature *(xxx.x)*	36.4 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG

US3402382
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

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

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

FDA-CBER-2022-1614-1767813

US3402382
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	16 AUG 2020
What was the treatment time? *(00:00-23:59)*	13:13 (24 HR)
Treatment Date and Time (derived)	16 AUG 2020 13:13
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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US3402382
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	16 AUG 2020
Collection time *(00:00-23:59)*	12:39 (24 HR)
Collection date and time (derived)	16 AUG 2020 12:39

FDA-CBER-2022-1614-1767815

US3402382
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

Collection date *(dd MMM yyyy)*			16 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:37	16 AUG 2020 12:37
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-1767816

US3402382
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767817

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:29:09

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**	96.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	16 AUG 2020 13:47
PC Open Date & Time	16 AUG 2020 13:33
PC Close Date & Time	16 AUG 2020 16:03

FDA-CBER-2022-1614-1767818

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:29:09

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**	94.5 °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	16 AUG 2020 21:45
PC Open Date & Time	16 AUG 2020 16:58
PC Close Date & Time	17 AUG 2020 11:59

FDA-CBER-2022-1614-1767819

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:29:09

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**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	17 AUG 2020 20:30
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

FDA-CBER-2022-1614-1767820

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:29:09

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**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 AUG 2020 13:23
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

FDA-CBER-2022-1614-1767821

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:29:09

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**	98.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	19 AUG 2020 19:17
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:29:09

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	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

FDA-CBER-2022-1614-1767823

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:29:09

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**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	21 AUG 2020 16:29
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

FDA-CBER-2022-1614-1767824

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:29:09

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**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	23 AUG 2020 10:54
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	16 AUG 2020 13:48
PC Open Date & Time	16 AUG 2020 13:33
PC Close Date & Time	16 AUG 2020 16:03

FDA-CBER-2022-1614-1767826

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	16 AUG 2020 21:46
PC Open Date & Time	16 AUG 2020 16:58
PC Close Date & Time	17 AUG 2020 11:59

FDA-CBER-2022-1614-1767827

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

FDA-CBER-2022-1614-1767828

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:29:09

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	18 AUG 2020 13:25
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767830

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09

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	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

FDA-CBER-2022-1614-1767831

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	21 AUG 2020 16:28
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:29:09

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	23 AUG 2020 10:55
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

FDA-CBER-2022-1614-1767833

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09

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-2022-1614-1767834

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	16 AUG 2020 13:49
PC Open Date & Time	16 AUG 2020 13:33
PC Close Date & Time	16 AUG 2020 16:03

FDA-CBER-2022-1614-1767835

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-2022-1614-1767836

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☑ Yes ☐
PC Time stamp	16 AUG 2020 21:47
PC Open Date & Time	16 AUG 2020 16:58
PC Close Date & Time	17 AUG 2020 11:59

FDA-CBER-2022-1614-1767837

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09

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-2022-1614-1767838

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

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09

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-2022-1614-1767840

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09

	Yes ☐
PC Time stamp	18 AUG 2020 13:26
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

FDA-CBER-2022-1614-1767841

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09

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-2022-1614-1767842

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09

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

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09

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-2022-1614-1767844

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

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09

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-2022-1614-1767846

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09

	Yes ☐
PC Time stamp	21 AUG 2020 16:29
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

FDA-CBER-2022-1614-1767847

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09

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-2022-1614-1767848

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09

	Yes ☐
PC Time stamp	23 AUG 2020 10:56
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

FDA-CBER-2022-1614-1767849

US3402382
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 17:29:09

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	23 AUG 2020 23:15
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-1767850

US3402382
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 09 Jun 2021 17:29:09

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	24 AUG 2020 19:22
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-1767851

US3402382
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	23 AUG 2020 23:15
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-1767852

US3402382
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 9
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	24 AUG 2020 19:22
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-1767853

US3402382
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

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-2022-1614-1767854

US3402382
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

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

US3402382
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	16 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-2022-1614-1767856

US3402382
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767857

US3402382
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	06 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-1767858

US3402382
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767859

US3402382
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT2

FDA-CBER-2022-1614-1767860

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	14 SEP 2020
Time of assessment *(00:00-23:59)*	11:30 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 11:30
Temperature *(xxx.x)*	36.3 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	64 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	58 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-1767861

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	14 SEP 2020
Time of assessment *(00:00-23:59)*	12:35 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 12:35
Temperature *(xxx.x)*	36.4 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	52 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	62 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-1767862

US3402382
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	14 SEP 2020

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

FDA-CBER-2022-1614-1767863

US3402382
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

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)*	14 SEP 2020
What was the treatment time? *(00:00-23:59)*	12:03 (24 HR)
Treatment Date and Time (derived)	14 SEP 2020 12:03
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

FDA-CBER-2022-1614-1767864

US3402382
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	14 SEP 2020
Collection time *(00:00-23:59)*	11:46 (24 HR)
Collection date and time (derived)	14 SEP 2020 11:46

US3402382
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

Collection date *(dd MMM yyyy)*			14 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:43	14 SEP 2020 11:43
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-1767866

US3402382
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767867

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:29:09

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**	97.4 °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	14 SEP 2020 12:35
PC Open Date & Time	14 SEP 2020 12:23
PC Close Date & Time	14 SEP 2020 14:53

FDA-CBER-2022-1614-1767868

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:29:09

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	14 SEP 2020 15:48
PC Close Date & Time	15 SEP 2020 11:59

FDA-CBER-2022-1614-1767869

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☐ No ☐
Please record your **TEMPERATURE in °F**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

FDA-CBER-2022-1614-1767870

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 3

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

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

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

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

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

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

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

FDA-CBER-2022-1614-1767871

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 4

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

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

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

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

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

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

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

FDA-CBER-2022-1614-1767872

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767873

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:29:09

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.

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

FDA-CBER-2022-1614-1767874

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:29:09

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.

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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.

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

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:29:09

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	14 SEP 2020 12:36
PC Open Date & Time	14 SEP 2020 12:23
PC Close Date & Time	14 SEP 2020 14:53

FDA-CBER-2022-1614-1767876

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:29:09

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	14 SEP 2020 15:48
PC Close Date & Time	15 SEP 2020 11:59

FDA-CBER-2022-1614-1767877

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

FDA-CBER-2022-1614-1767878

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

FDA-CBER-2022-1614-1767879

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767881

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767882

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767883

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09

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-2022-1614-1767884

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	14 SEP 2020 12:37
PC Open Date & Time	14 SEP 2020 12:23
PC Close Date & Time	14 SEP 2020 14:53

FDA-CBER-2022-1614-1767885

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-2022-1614-1767886

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	14 SEP 2020 15:48
PC Close Date & Time	15 SEP 2020 11:59

FDA-CBER-2022-1614-1767887

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09

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-2022-1614-1767888

	Yes ☐
PC Time stamp	
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09

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-2022-1614-1767890

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

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09

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-2022-1614-1767892

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

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-2022-1614-1767894

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

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09

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-2022-1614-1767896

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

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09

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-2022-1614-1767898

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

US3402382
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	21 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

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US3402382
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767901

US3402382
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	28 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-1767902

US3402382
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767903

US3402382
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	05 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-2022-1614-1767904

US3402382
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767905

US3402382
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT3

FDA-CBER-2022-1614-1767906

US3402382
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	12 OCT 2020
Time of assessment *(00:00-23:59)*	12:32 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 12:32
Temperature *(xxx.x)*	97.1 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	63 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402382
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

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

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

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US3402382
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	12 OCT 2020
Collection time *(00:00-23:59)*	12:35 (24 HR)
Collection date and time (derived)	12 OCT 2020 12:35

FDA-CBER-2022-1614-1767909

US3402382
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 18:24:29**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767910

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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	16 OCT 2020 08:25:33
Patient Cloud Open Date & Time	16 OCT 2020 00:01
Patient Cloud Close Date & Time	20 OCT 2020 23:59

FDA-CBER-2022-1614-1767911

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 OCT 2020 11:08:41
Patient Cloud Open Date & Time	23 OCT 2020 00:01
Patient Cloud Close Date & Time	27 OCT 2020 23:59

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Date and time of submission	31 OCT 2020 11:07:29
Patient Cloud Open Date & Time	30 OCT 2020 00:01
Patient Cloud Close Date & Time	03 NOV 2020 23:59

FDA-CBER-2022-1614-1767913

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-2022-1614-1767914

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767915

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 12:20:42
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 07:51:05
Patient Cloud Open Date & Time	24 NOV 2020 00:01
Patient Cloud Close Date & Time	28 NOV 2020 23:59

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 DEC 2020 11:28:06
Patient Cloud Open Date & Time	01 DEC 2020 00:01
Patient Cloud Close Date & Time	05 DEC 2020 23:59

FDA-CBER-2022-1614-1767918

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 DEC 2020 09:48:47
Patient Cloud Open Date & Time	08 DEC 2020 00:01
Patient Cloud Close Date & Time	12 DEC 2020 23:59

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 DEC 2020 09:37:10
Patient Cloud Open Date & Time	15 DEC 2020 00:01
Patient Cloud Close Date & Time	19 DEC 2020 23:59

FDA-CBER-2022-1614-1767920

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 DEC 2020 00:32:39
Patient Cloud Open Date & Time	22 DEC 2020 00:01
Patient Cloud Close Date & Time	26 DEC 2020 23:59

FDA-CBER-2022-1614-1767921

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 DEC 2020 06:53:00
Patient Cloud Open Date & Time	29 DEC 2020 00:01
Patient Cloud Close Date & Time	02 JAN 2021 23:59

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 JAN 2021 00:23:00
Patient Cloud Open Date & Time	05 JAN 2021 00:01
Patient Cloud Close Date & Time	09 JAN 2021 23:59

FDA-CBER-2022-1614-1767923

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 JAN 2021 18:50:51
Patient Cloud Open Date & Time	12 JAN 2021 00:01
Patient Cloud Close Date & Time	16 JAN 2021 23:59

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 JAN 2021 17:38:24
Patient Cloud Open Date & Time	19 JAN 2021 00:01
Patient Cloud Close Date & Time	23 JAN 2021 23:59

FDA-CBER-2022-1614-1767925

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 JAN 2021 00:05:34
Patient Cloud Open Date & Time	26 JAN 2021 00:01
Patient Cloud Close Date & Time	30 JAN 2021 23:59

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 FEB 2021 23:52:43
Patient Cloud Open Date & Time	02 FEB 2021 00:01
Patient Cloud Close Date & Time	06 FEB 2021 23:59

FDA-CBER-2022-1614-1767927

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 20:57:28
Patient Cloud Open Date & Time	09 FEB 2021 00:01
Patient Cloud Close Date & Time	13 FEB 2021 23:59

FDA-CBER-2022-1614-1767928

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 FEB 2021 00:13:11
Patient Cloud Open Date & Time	16 FEB 2021 00:01
Patient Cloud Close Date & Time	20 FEB 2021 23:59

FDA-CBER-2022-1614-1767929

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 FEB 2021 05:02:46
Patient Cloud Open Date & Time	23 FEB 2021 00:01
Patient Cloud Close Date & Time	27 FEB 2021 23:59

FDA-CBER-2022-1614-1767930

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAR 2021 08:54:43
Patient Cloud Open Date & Time	02 MAR 2021 00:01
Patient Cloud Close Date & Time	06 MAR 2021 23:59

FDA-CBER-2022-1614-1767931

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 MAR 2021 11:17:01
Patient Cloud Open Date & Time	09 MAR 2021 00:01
Patient Cloud Close Date & Time	13 MAR 2021 23:59

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 MAR 2021 10:49:30
Patient Cloud Open Date & Time	16 MAR 2021 00:01
Patient Cloud Close Date & Time	20 MAR 2021 23:59

FDA-CBER-2022-1614-1767933

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 MAR 2021 23:39:26
Patient Cloud Open Date & Time	23 MAR 2021 00:01
Patient Cloud Close Date & Time	27 MAR 2021 23:59

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 MAR 2021 23:59:39
Patient Cloud Open Date & Time	30 MAR 2021 00:01
Patient Cloud Close Date & Time	03 APR 2021 23:59

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 APR 2021 00:39:18
Patient Cloud Open Date & Time	06 APR 2021 00:01
Patient Cloud Close Date & Time	10 APR 2021 23:59

FDA-CBER-2022-1614-1767936

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767938

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 APR 2021 19:09:15
Patient Cloud Open Date & Time	20 APR 2021 00:01
Patient Cloud Close Date & Time	24 APR 2021 23:59

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAY 2021 17:07:55
Patient Cloud Open Date & Time	27 APR 2021 00:01
Patient Cloud Close Date & Time	01 MAY 2021 23:59

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767942

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

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

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

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767948

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767956

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

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

FDA-CBER-2022-1614-1767959

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767966

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767968

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767976

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

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

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767980

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767984

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767986

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767988

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767990

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767992

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767994

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767996

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1767998

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768002

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768004

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768006

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768008

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 DEC 2021 00:01
Patient Cloud Close Date & Time	01 JAN 2022 23:59

FDA-CBER-2022-1614-1768010

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

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

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

TIMEPOINT	DAY 537
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
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Generated On: 09 Jun 2021 17:29:09

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

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

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

US3402382
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	15 FEB 2022 00:01
Patient Cloud Close Date & Time	19 FEB 2022 23:59

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

US3402382
Folder: New Safety Follow Up Diary (1)
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	22 FEB 2022 00:01
Patient Cloud Close Date & Time	26 FEB 2022 23:59

FDA-CBER-2022-1614-1768026

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

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

US3402382
Folder: New Safety Follow Up Diary (1)
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	08 MAR 2022 00:01
Patient Cloud Close Date & Time	12 MAR 2022 23:59

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

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

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	22 MAR 2022 00:01
Patient Cloud Close Date & Time	26 MAR 2022 23:59

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

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768046

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-1768047

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768052

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768054

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

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

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768068

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768070

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

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

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

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

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

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768088

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768090

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

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

FDA-CBER-2022-1614-1768092

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09

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

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 23:41:33

US3402382
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **08 Mar 2021 22:30:13**
Generated On: 09 Jun 2021 17:29:09

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	09 NOV 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-1768096

US3402382
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **08 Mar 2021 22:30:13**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768097

US3402382
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **26 Apr 2021 23:42:26**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768098

US3402382
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **26 Apr 2021 23:42:26**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768099

US3402382
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **26 Apr 2021 23:42:26**
Generated On: 09 Jun 2021 17:29:09

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	11 JAN 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-1768100

US3402382
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **26 Apr 2021 23:42:26**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768101

US3402382
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **26 Apr 2021 23:42:26**
Generated On: 09 Jun 2021 17:29:09

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	8 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-2022-1614-1768102

US3402382
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **26 Apr 2021 23:42:26**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768103

US3402382
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **26 Apr 2021 23:42:26**
Generated On: 09 Jun 2021 17:29:09

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	18 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT4

FDA-CBER-2022-1614-1768104

US3402382
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **26 Apr 2021 23:42:26**
Generated On: 09 Jun 2021 17:29:09

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)	

FDA-CBER-2022-1614-1768105

US3402382
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Data signed: (b) (4) **26 Apr 2021 23:42:26**
Generated On: 09 Jun 2021 17:29:09

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.

US3402382
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **26 Apr 2021 23:42:26**
Generated On: 09 Jun 2021 17:29:09

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	18 MAR 2021
Collection time *(00:00-23:59)*	11:14 (24 HR)
Collection date and time (derived)	18 MAR 2021 11:14

US3402382
Folder: Visit 4 Day 209 (1)
Form: Continuing
Data signed: (b) (4) **26 Apr 2021 23:42:26**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768108

US3402382
Folder: Safety Call Day 239 (1)
Form: Safety Call
Data signed: (b) (4) **26 Apr 2021 23:42:26**
Generated On: 09 Jun 2021 17:29:09

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	9 APR 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-2022-1614-1768109

US3402382
Folder: Safety Call Day 239 (1)
Form: Continuing
Data signed: (b) (4) **26 Apr 2021 23:42:26**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768110

US3402382
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09

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-2022-1614-1768111

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

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: COVID-19 Contact
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

Date of Contact	26 AUG 2020
Time of Contact	07:00
Date and Time of Contact (derived)	26 AUG 2020 07:00
Type of Contact	Clinic Visit - Scheduled ●
	Clinical Visit - Unscheduled ○
	Safety Call ○
	Convalescent Tele-visit ○
Has the subject reported symptoms of SARS-COV-2?	Yes ●
	No ○

FDA-CBER-2022-1614-1768113

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

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
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- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-1768114

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	26 AUG 2020
Assessment Not Done	False
O2 Saturation	100 %
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 ☐

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

	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-2022-1614-1768116

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-2022-1614-1768117

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

Symptom Day

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

FDA-CBER-2022-1614-1768118

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	27 AUG 2020
Assessment Not Done	False
O2 Saturation	100 %
O2 Saturation Units	%
Temperature	98.2 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

	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
- [x] Day 4
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- [ ] Day 6
- [ ] Day 7
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- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [ ] Day 19
- [ ] Day 20
- [ ] Day 21
- [ ] Day 22
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- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-1768122

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	28 AUG 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	96.8 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 ☐

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

	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
- [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
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- [ ] Day 23
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- [ ] Day 28
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- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-1768126

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	29 AUG 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 ☐

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

	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 ☐

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

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-2022-1614-1768130

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	30 AUG 2020
Assessment Not Done	False
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 ☐

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

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

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

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
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- [ ] Day 6
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- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
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- [ ] Day 32

FDA-CBER-2022-1614-1768134

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	31 AUG 2020
Assessment Not Done	False
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
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FDA-CBER-2022-1614-1768138

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	01 SEP 2020
Assessment Not Done	False
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 ☐

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

	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-2022-1614-1768141

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [x] 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-2022-1614-1768142

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	02 SEP 2020
Assessment Not Done	False
O2 Saturation	100 %
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 ☐

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

	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-2022-1614-1768145

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [ ] Day 9
- [x] 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-2022-1614-1768146

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	03 SEP 2020
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	36.1 C
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 ☐

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

	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-2022-1614-1768149

Symptom Day

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

FDA-CBER-2022-1614-1768150

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	04 SEP 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	96.4 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

	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-2022-1614-1768153

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-2022-1614-1768154

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	05 SEP 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	96.0 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 ☐

FDA-CBER-2022-1614-1768157

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
- [x] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [ ] Day 19
- [ ] Day 20
- [ ] Day 21
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- [ ] Day 24
- [ ] Day 25
- [ ] Day 26
- [ ] Day 27
- [ ] Day 28
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- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-1768158

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	06 SEP 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	96.9 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

	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-2022-1614-1768161

Symptom Day

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

FDA-CBER-2022-1614-1768162

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	07 SEP 2020
Assessment Not Done	False
O2 Saturation	100 %
O2 Saturation Units	%
Temperature	36.4 C
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 ☐

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

	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
- [x] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [ ] Day 19
- [ ] Day 20
- [ ] Day 21
- [ ] Day 22
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- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-1768166

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	08 SEP 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	96.4 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

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

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

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
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- [ ] Day 21
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- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-1768170

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	09 SEP 2020
Assessment Not Done	False
O2 Saturation	100 %
O2 Saturation Units	%
Temperature	96.9 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

	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-2022-1614-1768173

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
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- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-1768174

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	10 SEP 2020
Assessment Not Done	False
O2 Saturation	95 %
O2 Saturation Units	%
Temperature	97.9 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

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

Nasal Congestion	None ■ Mild ☐ Moderate ☐ 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-2022-1614-1768177

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
- [x] 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-2022-1614-1768178

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	11 SEP 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	97.6 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

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

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

FDA-CBER-2022-1614-1768181

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
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- [ ] Day 25
- [ ] Day 26
- [ ] Day 27
- [ ] Day 28
- [ ] Day 29
- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-1768182

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	12 OCT 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.4 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

	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-2022-1614-1768185

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
- [x] Day 20
- [ ] Day 21
- [ ] Day 22
- [ ] Day 23
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- [ ] Day 25
- [ ] Day 26
- [ ] Day 27
- [ ] Day 28
- [ ] Day 29
- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-1768186

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	13 OCT 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	97.7 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 ☐

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

	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 ☐

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

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
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- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-1768190

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	25 AUG 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 ☐

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: COVID Diagnostic Test
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

Date of Visit	26 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	26 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

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Generate Next COVID-19 Assessment
Data signed: (b) (4) **26 Apr 2021 23:42:23**
Generated On: 09 Jun 2021 17:29:09

Generate Next COVID-19 Assessment	Yes ☐ No ■

FDA-CBER-2022-1614-1768195

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection
Data signed: (b) (4) **26 Apr 2021 23:42:24**
Generated On: 09 Jun 2021 17:29:09

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	28 AUG 2020
Day 5	No	
Day 7	No	01 SEP 2020
Day 9	No	
Day 14	Yes	08 SEP 2020
Day 21	No	
Day 28	No	

FDA-CBER-2022-1614-1768196

US3402382
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Data signed: (b) (4) **26 Apr 2021 23:42:24**
Generated On: 09 Jun 2021 17:29:09

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	SICKD1

FDA-CBER-2022-1614-1768197

US3402382
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Data signed: (b) (4) **26 Apr 2021 23:42:24**
Generated On: 09 Jun 2021 17:29:09

Were vital signs assessed?	Yes ● / No ○
Date of assessment *(dd MMM yyyy)*	26 AUG 2020
Time of assessment *(00:00-23:59)*	12:51 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 12:51
Height *(xxx.x)*	187.9 cm
Weight *(xxx.x)*	127.9 kg
Temperature *(xxx.x)*	99.5 F
Route of measurement	Oral ● / Axillary ○ / Other ○
If Other, specify	
Pulse *(xxx)*	137 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402382
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Data signed: (b) (4) **26 Apr 2021 23:42:24**
Generated On: 09 Jun 2021 17:29:09

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	26 AUG 2020

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

US3402382
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **26 Apr 2021 23:42:24**
Generated On: 09 Jun 2021 17:29:09

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ■ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	28 AUG 2020

FDA-CBER-2022-1614-1768200

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **26 Apr 2021 23:42:25**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768201

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **26 Apr 2021 23:42:25**
Generated On: 09 Jun 2021 17:29:09

Date of updated informed consent *(dd MMM yyyy)*	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ■ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ■
Date of unblinding *(dd MMM yyyy)*	23 JAN 2021
Participant randomization assignment	mRNA-1273 ☐ Placebo ■
Actual Dose 1	mRNA-1273 ☐ Placebo ■ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ■ Not Administered ☐
Will participant receive mRNA-1273?	Yes ■ No ☐
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Data signed: (b) (4) **26 Apr 2021 23:42:25**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768203

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **26 Apr 2021 23:42:25**
Generated On: 09 Jun 2021 17:29:09

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	23 JAN 2021
Time of assessment *(00:00-23:59)*	11:30 (24 HR)
Vital Signs Date and Time (derived)	23 JAN 2021 11:30
Temperature *(xxx.x)*	36.5 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	56 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	65 mmHg
Diastolic Blood Pressure units	MMHG

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **26 Apr 2021 23:42:25**
Generated On: 09 Jun 2021 17:29:09

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	23 JAN 2021
Time of assessment *(00:00-23:59)*	12:29 (24 HR)
Vital Signs Date and Time (derived)	23 JAN 2021 12:29
Temperature *(xxx.x)*	36.5 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	56 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	69 mmHg
Diastolic Blood Pressure units	MMHG

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Data signed: (b) (4) **26 Apr 2021 23:42:25**
Generated On: 09 Jun 2021 17:29:09

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

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

FDA-CBER-2022-1614-1768206

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Data signed: (b) (4) **26 Apr 2021 23:42:25**
Generated On: 09 Jun 2021 17:29:09

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	23 JAN 2021
What was the treatment time? *(00:00-23:59)*	11:50 (24 HR)
Treatment Date and Time (derived)	23 JAN 2021 11:50
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

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **26 Apr 2021 23:42:25**
Generated On: 09 Jun 2021 17:29:09

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	23 JAN 2021
Collection time *(00:00-23:59)*	11:19 (24 HR)
Collection date and time (derived)	23 JAN 2021 11:19

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **26 Apr 2021 23:42:24**
Generated On: 09 Jun 2021 17:29:09

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	23 JAN 2021
Collection time *(00:00 - 23:59)*	11:20
Collection Date and Time (derived)	23 JAN 2021 11:20

FDA-CBER-2022-1614-1768209

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Data signed: (b) (4) **26 Apr 2021 23:42:25**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768210

US3402382
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Data signed: (b) (4) **26 Apr 2021 23:42:26**
Generated On: 09 Jun 2021 17:29:09

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	1 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-2022-1614-1768211

US3402382
Folder: Safety Call OL-D8 (1)
Form: Continuing
Data signed: (b) (4) **26 Apr 2021 23:42:26**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768212

US3402382
Folder: OL-D29 (1)
Form: Visit Date
Data signed: (b) (4) **26 Apr 2021 23:42:24**
Generated On: 09 Jun 2021 17:29:09

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	19 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ■ Clinic ☐
Folder OID	OLD29

FDA-CBER-2022-1614-1768213

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **26 Apr 2021 23:42:24**
Generated On: 09 Jun 2021 17:29:09

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	19 FEB 2021
Time of assessment *(00:00-23:59)*	11:46 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 11:46
Temperature *(xxx.x)*	36.2 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	58 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	86 mmHg
Diastolic Blood Pressure units	MMHG

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **26 Apr 2021 23:42:24**
Generated On: 09 Jun 2021 17:29:09

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	19 FEB 2021
Time of assessment *(00:00-23:59)*	12:36 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 12:36
Temperature *(xxx.x)*	36.9 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	82 mmHg
Diastolic Blood Pressure units	MMHG

US3402382
Folder: OL-D29 (1)
Form: Physical Examination
Data signed: (b) (4) **26 Apr 2021 23:42:24**
Generated On: 09 Jun 2021 17:29:09

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	19 FEB 2021

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

FDA-CBER-2022-1614-1768216

US3402382
Folder: OL-D29 (1)
Form: Exposure
Data signed: (b) (4) **26 Apr 2021 23:42:24**
Generated On: 09 Jun 2021 17:29:09

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	19 FEB 2021
What was the treatment time? *(00:00-23:59)*	12:05 (24 HR)
Treatment Date and Time (derived)	19 FEB 2021 12:05
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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US3402382
Folder: OL-D29 (1)
Form: Continuing
Data signed: (b) (4) **26 Apr 2021 23:42:24**
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Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

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US3402382
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Data signed: (b) (4) **26 Apr 2021 23:42:26**
Generated On: 09 Jun 2021 17:29:09

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	

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US3402382
Folder: Safety Call OL-D36 (1)
Form: Continuing
Data signed: (b) (4) **26 Apr 2021 23:42:26**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768220

US3402382
Folder: OL-D57 (1)
Form: Visit Date
Data signed: (b) (4) **26 Apr 2021 23:42:24**
Generated On: 09 Jun 2021 17:29:09

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	18 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	OLD57

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US3402382
Folder: OL-D57 (1)
Form: Vital Signs
Data signed: (b) (4) **26 Apr 2021 23:42:24**
Generated On: 09 Jun 2021 17:29:09

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)	

US3402382
Folder: OL-D57 (1)
Form: Physical Examination
Data signed: (b) (4) **26 Apr 2021 23:42:24**
Generated On: 09 Jun 2021 17:29:09

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

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

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US3402382
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **26 Apr 2021 23:42:24**
Generated On: 09 Jun 2021 17:29:09

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	18 MAR 2021
Collection time *(00:00-23:59)*	11:14 (24 HR)
Collection date and time (derived)	18 MAR 2021 11:14

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US3402382
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **14 Mar 2021 14:49:44**
Generated On: 09 Jun 2021 17:29:09

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

If Yes, enter details on the Adverse Events form.

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US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **03 May 2021 22:58:39**
Generated On: 09 Jun 2021 17:29:09

AEID	USA-US059-2020-MRNA-1273-P301000002
Adverse event	ATRIAL FIBRILLATION
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 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)*	1 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ■ Grade 4 ☐
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	28 AUG 2020
Hospital Discharge Date *(dd MMM yyyy)*	1 SEP 2020
Admitted to ICU?	Yes ☐ No ■ Unknown ☐

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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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	

Narrative

SUBJECT PRESENTED IN OFFICE 26/AUG/2020 FOR A CONVALESCENT DAY 1 VISIT. HIS PULSE WAS NOTED TO BE 139. HE ALSO STATED THAT HE THOUGHT HE WAS HAVING SYMPTOMS OF AN URINARY INFECTION. HE WAS ADVISED TO GO TO THE EMERGENCY ROOM AT THAT POINT. WHICH HE DECLINED. HE WAS GIVEN LEVOFLOXACIN 500MG PO FOR 10 DAYS. WHEN HE CAME TO LEAVE HIS DAY 3 SALIVA SAMPLE2 28OCT2020 IT WAS NOTED THAT THE PATIENT WAS NOT ANY BETTER. PATIENT STATED THAT HE WAS UNSTEADY ON HIS FEET AND HAD FALLEN PRIOR TO COMING TO DROP OFF SAMPLE. IT WAS AGAIN RECOMMENDED THAT THE SUBJECT GO TO THE ER. WHICH HE DID.DUE TO SUBJECT FALLING HE HAD A CT OF THE HEAD AND BRAIN, THAT WERE NEGATIVE. ALSO A CHEST X-RAY THAT WAS NEGATIVE. SUBJECTS BLOOD PRESSURE IN THE ER WAS 86/70 HEART RATE 134 AND A RESP RATE OF 20. SUBJECT HAS VARIOUS LABS, OF NOTE WERE CRP 14, CO2 20, BUN 36, CREATININE 1.9. IT WAS

	THOUGHT THAT HE HAD UROSEPSIS AND WAS STARTED ON ROCEPHIN, WHILE AWAITING URINE AND BLOOD CULTURE RESULTS WHICH WERE NEGATIVE. SUBJECT WAS ADMITTED 28AUG2020 WITH A DIAGNOSIS OF ATRIAL FLUTTER. A CONULT WITH CARDIOLOGY WAS CONDUCTED, AND PATIENT WAS STARTED ON 5 MG ELIQUIS DAILY AND WILL FOLLOW UP ON AN OUT PATIENT BASIS. COVID 19 TEST PREFORMED 26AUG2020 WITH A NEGATIVE RESULT. SUBJECTS HEART RATE HAS RETURNED TO NORMAL WITH THE HELP OF MEDICATION WHICH IS CAPTURES ON THE CONMED LOG.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **03 May 2021 22:58:39**
Generated On: 09 Jun 2021 17:29:09

AEID	
Adverse event	URINARY TRACT INFECTION
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)*	26 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)*	6 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ■ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ■ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Data signed: (b) (4) **03 May 2021 22:58:39**
Generated On: 09 Jun 2021 17:29:09

AEID	
Adverse event	FATIGUE
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)*	18 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)*	24 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 ☐
Number of Days in ICU	

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

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **08 Apr 2021 23:41:50**
Generated On: 09 Jun 2021 17:29:09

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

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

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **08 Apr 2021 23:41:50**
Generated On: 09 Jun 2021 17:29:09

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

FDA-CBER-2022-1614-1768235

	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)*	21 JUL 2020
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **08 Apr 2021 23:41:50**
Generated On: 09 Jun 2021 17:29:09

Name of Medication	ASPIRIN
Prophylaxis	Yes ■ No ☐
Indication	HEART ATTACK PREVENTION
Dose per administration	81
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-2022-1614-1768237

	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)*	25 AUG 2008
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 ■

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **08 Apr 2021 23:41:50**
Generated On: 09 Jun 2021 17:29:09

Name of Medication	VIAGARA
Prophylaxis	Yes ☐ No ■
Indication	ERECTILE DYSFUNCTION
Dose per administration	100
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-2022-1614-1768239

	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)*	25 AUG 2008
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 ☐

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **08 Apr 2021 23:41:50**
Generated On: 09 Jun 2021 17:29:09

Name of Medication	METOPROLOL ER
Prophylaxis	Yes ☐ No ■
Indication	HYPERTENSION
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-2022-1614-1768241

	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)*	25 APR 2008
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 ■

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **08 Apr 2021 23:41:50**
Generated On: 09 Jun 2021 17:29:09

Name of Medication	ATORVASTATIN
Prophylaxis	Yes ☐ No ■
Indication	HYPERLIPIDEMIA
Dose per administration	40
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-2022-1614-1768243

	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)*	10 FEB 2015
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 ■

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **08 Apr 2021 23:41:50**
Generated On: 09 Jun 2021 17:29:09

Name of Medication	TAMSULOSIN
Prophylaxis	Yes ☐ No ■
Indication	BENIGN PROSTATIC HYPERTROPHY
Dose per administration	0.4
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)*	01 SEP 2017
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **08 Apr 2021 23:41:50**
Generated On: 09 Jun 2021 17:29:09

Name of Medication	FEBUXOSTAT
Prophylaxis	Yes ☐ No ■
Indication	GOUT
Dose per administration	40
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-2022-1614-1768247

	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)*	25 OCT 2017
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **08 Apr 2021 23:41:50**
Generated On: 09 Jun 2021 17:29:09

Name of Medication	VOLTAREN 1%
Prophylaxis	Yes ☐ No ■
Indication	OSTEOARTHRITIS BILATERAL HIPS
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ■ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ■ Subcutaneous ☐ Transdermal ☐

FDA-CBER-2022-1614-1768249

	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)*	25 APR 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 ■

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **08 Apr 2021 23:41:50**
Generated On: 09 Jun 2021 17:29:09

Name of Medication	OZEMPIC
Prophylaxis	Yes ☐ No ■
Indication	DIABETES TYPE 2
Dose per administration	1
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ■ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ■ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-1768251

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	05 NOV 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 ☐

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **08 Apr 2021 23:41:50**
Generated On: 09 Jun 2021 17:29:09

Name of Medication	DULOXETINE
Prophylaxis	Yes ☐ No ■
Indication	ANXIETY
Dose per administration	60
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-2022-1614-1768253

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	05 NOV 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 ■

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Data signed: (b) (4) **08 Apr 2021 23:41:50**
Generated On: 09 Jun 2021 17:29:09

Name of Medication	JARDIANCE
Prophylaxis	Yes ☐ No ■
Indication	DIABETES TYPE 2
Dose per administration	25
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-2022-1614-1768255

	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)*	18 APR 2017
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Data signed: (b) (4) **08 Apr 2021 23:41:50**
Generated On: 09 Jun 2021 17:29:09

Name of Medication	HYDROCODONE
Prophylaxis	Yes ☐ No ■
Indication	OSTEOARTHRITIS
Dose per administration	5
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	31 OCT 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 ■

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Data signed: (b) (4) **08 Apr 2021 23:41:50**
Generated On: 09 Jun 2021 17:29:09

Name of Medication	COLACE
Prophylaxis	Yes ☐ No ■
Indication	CONSTIPATION
Dose per administration	100
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-2022-1614-1768259

	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)*	04 NOV 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 ■

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Data signed: (b) (4) **08 Apr 2021 23:41:50**
Generated On: 09 Jun 2021 17:29:09

Name of Medication	LANTUS SOLOSTAR
Prophylaxis	Yes ☐ No ■
Indication	TYPE 2 DIABETES
Dose per administration	100
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	UNITS
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)*	04 NOV 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 ■

Name of Medication	ELIQUIS
Prophylaxis	Yes ☐ No ■
Indication	ATRIAL FIBRILLATION
Dose per administration	5
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	28 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 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 ■

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Data signed: (b) (4) **08 Apr 2021 23:41:50**
Generated On: 09 Jun 2021 17:29:09

Name of Medication	LEVOFLOXACIN
Prophylaxis	Yes ☐ No ■
Indication	URINARY TRACT INFECTION BACTERIA
Dose per administration	500
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

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	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	28 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	08 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 ■

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Data signed: (b) (4) **08 Apr 2021 23:41:50**
Generated On: 09 Jun 2021 17:29:09

Name of Medication	KEFLEX
Prophylaxis	Yes ☐ No ■
Indication	URINARY TRACT INFECTION
Dose per administration	500
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-2022-1614-1768267

	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)*	26 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	06 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 ■

US3402382
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **08 Apr 2021 23:41:50**
Generated On: 09 Jun 2021 17:29:09

Were any concomitant procedures performed?	Yes ■ No ☐

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-1768269

US3402382
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures
Data signed: (b) (4) **08 Apr 2021 23:41:50**
Generated On: 09 Jun 2021 17:29:09

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
28 AUG 2020	COMPUTED TOMOGRAPHY HEAD/BRAIN W/O CONTRAST	Adverse Event	
28 AUG 2020	CHEST XRAY	Adverse Event	

FDA-CBER-2022-1614-1768270

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	

US3402382
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:29:09

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

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Data signed: (b) (4) **26 Apr 2021 23:42:25**
Generated On: 09 Jun 2021 17:29:09

SAEID	USA-US059-2020-MRNA-1273-P301000002
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form (1)
Data signed: (b) (4) **26 Apr 2021 23:42:25**
Generated On: 09 Jun 2021 17:29:09

SAEID	USA-US059-2020-MRNA-1273-P301000002
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	02/SEP/2020 09:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form (2)
Data signed: (b) (4) **26 Apr 2021 23:42:25**
Generated On: 09 Jun 2021 17:29:09

SAEID	USA-US059-2020-MRNA-1273-P301000002
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	14/SEP/2020 16:29
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

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form (3)
Data signed: (b) (4) **26 Apr 2021 23:42:25**
Generated On: 09 Jun 2021 17:29:09

SAEID	USA-US059-2020-MRNA-1273-P301000002
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	30/SEP/2020 17:21
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

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form (4)
Data signed: (b) (4) **26 Apr 2021 23:42:25**
Generated On: 09 Jun 2021 17:29:09

SAEID	USA-US059-2020-MRNA-1273-P301000002
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	30/OCT/2020 14:04
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-1768277

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form (5)
Data signed: (b) (4) **26 Apr 2021 23:42:25**
Generated On: 09 Jun 2021 17:29:09

SAEID	USA-US059-2020-MRNA-1273-P301000002
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	02/NOV/2020 14:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-1768278

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form (6)
Data signed: (b) (4) **26 Apr 2021 23:42:25**
Generated On: 09 Jun 2021 17:29:09

SAEID	USA-US059-2020-MRNA-1273-P301000002
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	09/NOV/2020 11:14
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

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form (7)
Data signed: (b) (4) **26 Apr 2021 23:42:25**
Generated On: 09 Jun 2021 17:29:09

SAEID	USA-US059-2020-MRNA-1273-P301000002
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	08/MAR/2021 11:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form (8)
Data signed: (b) (4) **26 Apr 2021 23:42:25**
Generated On: 09 Jun 2021 17:29:09

SAEID	USA-US059-2020-MRNA-1273-P301000002
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	09/MAR/2021 10:33
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

US3402382 (Prod: Meridian Clinical Research, LLC)

US3402382
Form: Participant Creation
Generated On: 09 Jun 2021 17:29:09
Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'US3402382'	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:29:15

US3402382
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:16:25

US3402382
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '16 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:29:16

US3402382
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:16:25

US3402382
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered 'SCRN'	System	16 Aug 2020 17:16:25

FDA-CBER-2022-1614-1768287

US3402382
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:29:09
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered (b) (6) 1953'	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:29:17

FDA-CBER-2022-1614-1768288

US3402382
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:29:09
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '66'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

US3402382
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:29:09
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered 'YEARS'	System	17 Aug 2020 11:53:44

US3402382
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:29:09
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered '67'	System	16 Aug 2020 17:17:02

FDA-CBER-2022-1614-1768291

US3402382
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:29:09
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'Male (M)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

US3402382
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:29:09
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

US3402382
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:29:09
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '1'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

US3402382
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:29:09
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

FDA-CBER-2022-1614-1768295

US3402382
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:29:09
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

FDA-CBER-2022-1614-1768296

US3402382
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:29:09
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

US3402382
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:29:09
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

US3402382
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:29:09
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

US3402382
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:29:09
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

FDA-CBER-2022-1614-1768300

US3402382
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:29:09
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

FDA-CBER-2022-1614-1768301

US3402382
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:29:09
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

US3402382
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:29:09
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '16 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:02

US3402382
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:29:09
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered 'Aug 2020'	System	16 Aug 2020 17:17:02

US3402382
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:29:09
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered '2020'	System	16 Aug 2020 17:17:02

US3402382
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:29:09
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'Amendment 2 (2)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:02

US3402382
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:29:09
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:02

US3402382
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:29:09
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:02

US3402382
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:29:09
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:02

US3402382
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:29:09
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:02

US3402382
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:29:09
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:29:16

US3402382
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:29:09
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered '1'	System	16 Aug 2020 17:17:08

US3402382
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 09 Jun 2021 17:29:09
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:08

US3402382
Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 17:29:09
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:54:27

US3402382
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:29:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:00:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:00:19
Data point term sent to Coder	System	17 Aug 2020 11:55:16
User entered 'TYPE 2 DIABETES'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:54:50

US3402382
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:29:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'UN UNK 1995'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:54:50

US3402382
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:54:50

US3402382
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:29:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:54:50

US3402382
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:29:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:54:50

US3402382
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:29:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:54:50

US3402382
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:29:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered 'Jan 1995'	System	17 Aug 2020 11:54:50

US3402382
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:29:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered '1995'	System	17 Aug 2020 11:54:50

US3402382
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:29:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered empty.	System	17 Aug 2020 11:54:50

US3402382
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:29:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered empty.	System	17 Aug 2020 11:54:50

US3402382
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:29:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Ligament rupture, LLT: Anterior cruciate ligament tear - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 07:08:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 07:08:14
Data point term sent to Coder	System	17 Aug 2020 11:55:15
User entered 'TORN ACL RIGHT LEG'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:10

US3402382
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:29:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'UN UNK 2008'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:10

US3402382
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:10

US3402382
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:29:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:10

US3402382
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:29:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:10

US3402382
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:29:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:10

US3402382
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:29:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered 'Jan 2008'	System	17 Aug 2020 11:55:10

US3402382
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:29:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered '2008'	System	17 Aug 2020 11:55:10

FDA-CBER-2022-1614-1768332

US3402382
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:29:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered empty.	System	17 Aug 2020 11:55:10

FDA-CBER-2022-1614-1768333

US3402382
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:29:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered empty.	System	17 Aug 2020 11:55:10

FDA-CBER-2022-1614-1768334

US3402382
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:29:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:02:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:02:45
Data point term sent to Coder	System	17 Aug 2020 11:56:16
User entered 'HYPERLIPIDEMIA'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:26

US3402382
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:29:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'UN UNK 2010'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:26

US3402382
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:26

US3402382
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:29:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:26

FDA-CBER-2022-1614-1768338

US3402382
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:29:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:26

US3402382
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:29:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:26

US3402382
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:29:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered 'Jan 2010'	System	17 Aug 2020 11:55:26

FDA-CBER-2022-1614-1768341

US3402382
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:29:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered '2010'	System	17 Aug 2020 11:55:26

FDA-CBER-2022-1614-1768342

US3402382
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:29:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered empty.	System	17 Aug 2020 11:55:26

FDA-CBER-2022-1614-1768343

US3402382
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:29:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered empty.	System	17 Aug 2020 11:55:26

FDA-CBER-2022-1614-1768344

US3402382
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:29:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:02:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:02:45
Data point term sent to Coder	System	17 Aug 2020 11:56:16
User entered 'HYPERTENSION'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:39

US3402382
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:29:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'UN UNK 2000'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:39

US3402382
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:39

US3402382
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:29:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:39

FDA-CBER-2022-1614-1768348

US3402382
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:29:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:39

FDA-CBER-2022-1614-1768349

US3402382
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:29:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:39

US3402382
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:29:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered 'Jan 2000'	System	17 Aug 2020 11:55:39

FDA-CBER-2022-1614-1768351

US3402382
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:29:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered '2000'	System	17 Aug 2020 11:55:39

FDA-CBER-2022-1614-1768352

US3402382
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:29:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered empty.	System	17 Aug 2020 11:55:39

US3402382
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:29:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered empty.	System	17 Aug 2020 11:55:39

FDA-CBER-2022-1614-1768354

US3402382
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:29:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User closed query 'CDM RQ: Per previous query response, please update the Condition Term to include the location.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 15:40:08
Query 'CDM RQ: Per previous query response, please update the Condition Term to include the location.' answered with ' LEFT FOOT' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 18:03:22
User opened query 'CDM RQ: Per previous query response, please update the Condition Term to include the location.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:11:56
User closed query 'Per DM CLR: Please specify the location of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:11:56
Query 'Per DM CLR: Please specify the location of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'LEFT BIG TOE' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	22 Sep 2020 18:02:07
User opened query 'Per DM CLR: Please specify the location of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:12:56
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:02:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:02:46
Data point term sent to Coder	System	17 Aug 2020 11:56:16
User entered 'GOUT'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:48

FDA-CBER-2022-1614-1768355

US3402382
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:29:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'UN UNK 2008'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:48

US3402382
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:48

US3402382
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:29:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:48

US3402382
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:29:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:48

US3402382
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:29:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:48

US3402382
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:29:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered 'Jan 2008'	System	17 Aug 2020 11:55:48

FDA-CBER-2022-1614-1768361

US3402382
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:29:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered '2008'	System	17 Aug 2020 11:55:48

FDA-CBER-2022-1614-1768362

US3402382
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:29:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered empty.	System	17 Aug 2020 11:55:48

US3402382
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:29:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered empty.	System	17 Aug 2020 11:55:48

FDA-CBER-2022-1614-1768364

US3402382
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:29:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:47:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:47:12
Data point term sent to Coder	System	17 Aug 2020 20:47:03
User entered 'ERECTILE DYSFUNCTION'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:46:55

US3402382
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:29:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '25 Aug 2008'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:46:55

US3402382
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:46:55

US3402382
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:29:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:46:55

US3402382
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:29:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:46:55

US3402382
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:29:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:46:55

US3402382
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:29:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered 'Aug 2008'	System	17 Aug 2020 20:46:55

US3402382
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:29:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered '2008'	System	17 Aug 2020 20:46:55

FDA-CBER-2022-1614-1768372

US3402382
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:29:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered empty.	System	17 Aug 2020 20:46:55

US3402382
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:29:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered empty.	System	17 Aug 2020 20:46:55

FDA-CBER-2022-1614-1768374

US3402382
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:29:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:49:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:49:15
Data point term sent to Coder	System	17 Aug 2020 20:48:03
User entered 'BENIGN PROSTATIC HYPERTROPHY'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:47:24

US3402382
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:29:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '01 Sep 2017'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:47:24

US3402382
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:47:24

US3402382
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:29:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:47:24

US3402382
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:29:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:47:24

FDA-CBER-2022-1614-1768379

US3402382
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:29:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:47:24

US3402382
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:29:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered 'Sep 2017'	System	17 Aug 2020 20:47:24

US3402382
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:29:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered '2017'	System	17 Aug 2020 20:47:24

FDA-CBER-2022-1614-1768382

US3402382
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:29:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered empty.	System	17 Aug 2020 20:47:24

FDA-CBER-2022-1614-1768383

US3402382
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:29:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered empty.	System	17 Aug 2020 20:47:24

FDA-CBER-2022-1614-1768384

US3402382
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:29:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:49:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:49:15
Data point term sent to Coder	System	17 Aug 2020 20:48:04
User entered 'BILATERAL HIP OSTEOARTHRITIS'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:01

US3402382
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:29:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '25 Apr 2018'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:01

US3402382
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:01

US3402382
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:29:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:01

FDA-CBER-2022-1614-1768388

US3402382
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:29:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:01

FDA-CBER-2022-1614-1768389

US3402382
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:29:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:01

US3402382
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:29:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered 'Apr 2018'	System	17 Aug 2020 20:48:01

FDA-CBER-2022-1614-1768391

US3402382
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:29:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered '2018'	System	17 Aug 2020 20:48:01

FDA-CBER-2022-1614-1768392

US3402382
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:29:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered empty.	System	17 Aug 2020 20:48:01

US3402382
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:29:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered empty.	System	17 Aug 2020 20:48:01

FDA-CBER-2022-1614-1768394

US3402382
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:29:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
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)	17 Aug 2020 20:50:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:50:16
Data point term sent to Coder	System	17 Aug 2020 20:49:04
User entered 'ANXIETY'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:19

US3402382
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:29:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '05 Nov 2018'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:19

US3402382
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:19

US3402382
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:29:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:19

FDA-CBER-2022-1614-1768398

US3402382
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:29:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:19

FDA-CBER-2022-1614-1768399

US3402382
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:29:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:19

US3402382
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:29:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered 'Nov 2018'	System	17 Aug 2020 20:48:19

FDA-CBER-2022-1614-1768401

US3402382
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:29:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered '2018'	System	17 Aug 2020 20:48:19

FDA-CBER-2022-1614-1768402

US3402382
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:29:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered empty.	System	17 Aug 2020 20:48:19

US3402382
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:29:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered empty.	System	17 Aug 2020 20:48:19

FDA-CBER-2022-1614-1768404

US3402382
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:29:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:50:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:50:16
Data point term sent to Coder	System	17 Aug 2020 20:49:04
User entered 'CONSTIPATION'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:37

US3402382
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:29:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '04 Nov 2019'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:37

US3402382
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:37

US3402382
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:29:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 13:32:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 13:32:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 13:32:20
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 20:48:37
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:37

US3402382
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:29:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:37

FDA-CBER-2022-1614-1768409

US3402382
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:29:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:37

US3402382
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:29:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered 'Nov 2019'	System	17 Aug 2020 20:48:37

US3402382
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:29:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered '2019'	System	17 Aug 2020 20:48:37

US3402382
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:29:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered empty.	System	17 Aug 2020 20:48:37

FDA-CBER-2022-1614-1768413

US3402382
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:29:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered empty.	System	17 Aug 2020 20:48:37

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '16 Aug 2020'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '12:21'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45

FDA-CBER-2022-1614-1768417

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered '16 Aug 2020 12:21'	System	17 Aug 2020 11:57:45

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '74' in	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45
DataPoint set to visible.	System	16 Aug 2020 17:17:08

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '282' lb	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45
DataPoint set to visible.	System	16 Aug 2020 17:17:08

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
Amendment Manager: User entered '36.28236'	System	16 Sep 2020 23:59:08
User entered '36.3'	System	17 Aug 2020 11:57:45
DataPoint set to visible.	System	16 Aug 2020 17:17:08

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered 'kg/m2'	System	17 Aug 2020 11:57:45
DataPoint set to visible.	System	16 Aug 2020 17:17:08

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 19:29:36
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 19:29:36
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45

FDA-CBER-2022-1614-1768425

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 19:29:36
User entered '89'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered 'bpm'	System	17 Aug 2020 11:57:45

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 19:29:36
User entered '14'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered 'breaths/min'	System	17 Aug 2020 11:57:45

FDA-CBER-2022-1614-1768429

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 19:29:36
User entered '100'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered 'mmHg'	System	17 Aug 2020 11:57:45

FDA-CBER-2022-1614-1768431

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 19:29:36
User entered '62'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User entered 'mmHg'	System	17 Aug 2020 11:57:45

FDA-CBER-2022-1614-1768433

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54

FDA-CBER-2022-1614-1768434

US3402382
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54

FDA-CBER-2022-1614-1768435

US3402382
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 17:29:09
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:58:08

FDA-CBER-2022-1614-1768436

US3402382
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 17:29:09
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	24 Sep 2020 10:23:49
Comment added 'PLEASE ADVISE ON RESOLUTION AS DATE IS CORRECT'.	Tammy Kohn (b) (4) (b) (4)	22 Sep 2020 15:16:23
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 17:15:50
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	27 Aug 2020 13:32:50
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	26 Aug 2020 19:17:20
User entered '16 Aug 2020'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:58:08

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

FDA-CBER-2022-1614-1768442

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

FDA-CBER-2022-1614-1768449

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered 'TOWN (b) (6) '	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

FDA-CBER-2022-1614-1768451

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '1'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

FDA-CBER-2022-1614-1768456

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:29:09
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:48
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

FDA-CBER-2022-1614-1768458

US3402382
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:00:26

US3402382
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '16 Aug 2020'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:00:26

FDA-CBER-2022-1614-1768460

US3402382
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:00:26

US3402382
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered 'VISIT1'	System	17 Aug 2020 12:00:26

FDA-CBER-2022-1614-1768462

US3402382
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:29:09
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '16 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:34:11

FDA-CBER-2022-1614-1768463

US3402382
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:29:09
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:54:19
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:54:19
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Aug 2020 16:34:11
User entered '186501' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:34:11

US3402382
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:29:09
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:34:11

FDA-CBER-2022-1614-1768465

US3402382
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:29:09
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)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:00:45

US3402382
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:29:09

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)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:00:45

US3402382
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:29:09
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:00:45

US3402382
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:29:09
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:00:45

US3402382
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:29:09
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:00:45

US3402382
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:29:09
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:29
User closed query 'Per CDM: This field requires yes or no. Please complete' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:08:23
Query 'Per CDM: This field requires yes or no. Please complete' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	03 Nov 2020 13:01:46
User entered 'No (N)'	Tammy Kohn (b) (4)	03 Nov 2020 13:01:38
User opened query 'Per CDM: This field requires yes or no. Please complete' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 11:33:47
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:22:18
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:33:32

FDA-CBER-2022-1614-1768471

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:29:09
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 19:29:14
User entered '74' in	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:29:09
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 19:29:14
User entered '282' lb	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:29:09
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 19:29:14
User entered '74' in	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:29:09
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 19:29:14
User entered '282' lb	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '16 Aug 2020'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

FDA-CBER-2022-1614-1768478

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '12:21'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered '16 Aug 2020 12:21'	System	17 Aug 2020 12:02:13

FDA-CBER-2022-1614-1768480

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '36.3' C reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	17 Sep 2020 12:15:36
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

FDA-CBER-2022-1614-1768481

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

FDA-CBER-2022-1614-1768482

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

FDA-CBER-2022-1614-1768483

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '89'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

FDA-CBER-2022-1614-1768484

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered 'bpm'	System	17 Aug 2020 12:02:13

FDA-CBER-2022-1614-1768485

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '14'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

FDA-CBER-2022-1614-1768486

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered 'breaths/min'	System	17 Aug 2020 12:02:13

FDA-CBER-2022-1614-1768487

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '100'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

FDA-CBER-2022-1614-1768488

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered 'mmHg'	System	17 Aug 2020 12:02:13

FDA-CBER-2022-1614-1768489

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '62'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered 'mmHg'	System	17 Aug 2020 12:02:13

FDA-CBER-2022-1614-1768491

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:29:09
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 19:29:14
User entered '74' in	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:29:09
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 19:29:14
User entered '282' lb	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

FDA-CBER-2022-1614-1768494

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '16 Aug 2020'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

FDA-CBER-2022-1614-1768496

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
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)	17 Aug 2020 19:40:31
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 MINUTES ' (Site from System).	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:24
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	17 Aug 2020 12:02:13
User entered '13:45'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered '16 Aug 2020 13:45'	System	17 Aug 2020 12:02:13

FDA-CBER-2022-1614-1768498

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 12:14:55
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	17 Sep 2020 12:14:55
User entered '36.4' C reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	17 Sep 2020 12:14:55
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:59:08
User entered '96.0' F	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

FDA-CBER-2022-1614-1768501

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '60'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

FDA-CBER-2022-1614-1768502

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered 'bpm'	System	17 Aug 2020 12:02:13

FDA-CBER-2022-1614-1768503

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '14'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered 'breaths/min'	System	17 Aug 2020 12:02:13

FDA-CBER-2022-1614-1768505

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '100'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered 'mmHg'	System	17 Aug 2020 12:02:13

FDA-CBER-2022-1614-1768507

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '76'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered 'mmHg'	System	17 Aug 2020 12:02:13

US3402382
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 17:29:09
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Sep 2020 12:19:19
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:35

US3402382
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 17:29:09
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Sep 2020 12:19:19
User entered '16 Aug 2020'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:35

FDA-CBER-2022-1614-1768511

US3402382
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768512

US3402382
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:49

US3402382
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
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)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:49

US3402382
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered 'MRNA-1273 OR PLACEBO'	System	16 Aug 2020 17:17:49

US3402382
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '16 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:49

US3402382
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '13:13'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:49

US3402382
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered '16 Aug 2020 13:13'	System	16 Aug 2020 17:17:49

US3402382
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Left Arm (LEFT ARM)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:49

US3402382
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered 'ONCE'	System	16 Aug 2020 17:17:49

US3402382
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered 'INTRAMUSCULAR'	System	16 Aug 2020 17:17:49

US3402382
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:04

US3402382
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '16 Aug 2020'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:04

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US3402382
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '12:39'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:04

US3402382
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered '16 Aug 2020 12:39'	System	17 Aug 2020 12:03:04

FDA-CBER-2022-1614-1768525

US3402382
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 17:29:09
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '16 Aug 2020'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:20

US3402382
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:29:09
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:20

FDA-CBER-2022-1614-1768527

US3402382
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:29:09
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:20

US3402382
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:29:09
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '12:37'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:20

US3402382
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:29:09
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered '16 Aug 2020 12:37'	System	17 Aug 2020 12:03:20

US3402382
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:29:09
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:20

US3402382
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:29:09
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:20

US3402382
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:29:09
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:20

US3402382
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:29:09
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered empty.	System	17 Aug 2020 12:03:20

US3402382
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:25

US3402382
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered '1'	System	17 Aug 2020 12:03:25

FDA-CBER-2022-1614-1768536

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:46:43', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '62fcd2c3-ff8f-42d3-84e1-1855ef735627'	System	16 Aug 2020 17:47:22
User entered 'Yes (Y)'	System	16 Aug 2020 17:47:22

FDA-CBER-2022-1614-1768538

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:47:01', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '62fcd2c3-ff8f-42d3-84e1-1855ef735627'	System	16 Aug 2020 17:47:22
User entered '96.0'	System	16 Aug 2020 17:47:22

FDA-CBER-2022-1614-1768539

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:47:09', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '62fcd2c3-ff8f-42d3-84e1-1855ef735627'	System	16 Aug 2020 17:47:22
User entered 'No (N)'	System	16 Aug 2020 17:47:22

FDA-CBER-2022-1614-1768540

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:47:19', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '62fcd2c3-ff8f-42d3-84e1-1855ef735627'	System	16 Aug 2020 17:47:22
User entered '16 Aug 2020 13:47'	System	16 Aug 2020 17:47:22

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '16 Aug 2020 13:33'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768542

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '16 Aug 2020 16:03'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 1, after vaccination (at home)'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768544

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:44:34', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '31ed431e-7ac6-4760-8add-820dd01d7f0f'	System	17 Aug 2020 01:45:12
User entered 'Yes (Y)'	System	17 Aug 2020 01:45:12

FDA-CBER-2022-1614-1768545

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:44:45', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '31ed431e-7ac6-4760-8add-820dd01d7f0f'	System	17 Aug 2020 01:45:12
User entered '94.5'	System	17 Aug 2020 01:45:12

FDA-CBER-2022-1614-1768546

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:44:56', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '31ed431e-7ac6-4760-8add-820dd01d7f0f'	System	17 Aug 2020 01:45:12
User entered 'No (N)'	System	17 Aug 2020 01:45:12

FDA-CBER-2022-1614-1768547

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:45:10', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '31ed431e-7ac6-4760-8add-820dd01d7f0f'	System	17 Aug 2020 01:45:12
User entered '16 Aug 2020 21:45'	System	17 Aug 2020 01:45:12

FDA-CBER-2022-1614-1768548

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '16 Aug 2020 16:58'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768549

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '17 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 2'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:29:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-17T20:29:32', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ac33e71-88f1-44de-abcc-0d37b480faff'	System	18 Aug 2020 00:30:06
User entered 'Yes (Y)'	System	18 Aug 2020 00:30:06

FDA-CBER-2022-1614-1768552

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:29:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-17T20:29:43', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ac33e71-88f1-44de-abcc-0d37b480faff'	System	18 Aug 2020 00:30:06
User entered '98.0'	System	18 Aug 2020 00:30:06

FDA-CBER-2022-1614-1768553

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:29:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-17T20:29:50', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ac33e71-88f1-44de-abcc-0d37b480faff'	System	18 Aug 2020 00:30:06
User entered 'No (N)'	System	18 Aug 2020 00:30:06

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-17T20:30:03', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ac33e71-88f1-44de-abcc-0d37b480faff'	System	18 Aug 2020 00:30:06
User entered '17 Aug 2020 20:30'	System	18 Aug 2020 00:30:06

FDA-CBER-2022-1614-1768555

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768556

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 3'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768558

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:29:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:23:16', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'f2cd9b2d-a78d-4b2a-9f1e-22ede58b7e58'	System	18 Aug 2020 17:23:58
User entered 'Yes (Y)'	System	18 Aug 2020 17:23:58

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US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:29:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:23:31', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'f2cd9b2d-a78d-4b2a-9f1e-22ede58b7e58'	System	18 Aug 2020 17:23:58
User entered '98.0'	System	18 Aug 2020 17:23:58

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:29:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:23:36', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'f2cd9b2d-a78d-4b2a-9f1e-22ede58b7e58'	System	18 Aug 2020 17:23:58
User entered 'No (N)'	System	18 Aug 2020 17:23:58

FDA-CBER-2022-1614-1768561

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:23:55', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'f2cd9b2d-a78d-4b2a-9f1e-22ede58b7e58'	System	18 Aug 2020 17:23:58
User entered '18 Aug 2020 13:23'	System	18 Aug 2020 17:23:58

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

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US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 4'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:29:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:17:01', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '70cce1e5-f0dc-4dd6-a0f6-d4bd7b86555e'	System	19 Aug 2020 23:17:55
User entered 'Yes (Y)'	System	19 Aug 2020 23:17:55

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US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:29:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:17:17', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '70cce1e5-f0dc-4dd6-a0f6-d4bd7b86555e'	System	19 Aug 2020 23:17:55
User entered '98.1'	System	19 Aug 2020 23:17:55

FDA-CBER-2022-1614-1768567

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:29:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:17:24', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '70cce1e5-f0dc-4dd6-a0f6-d4bd7b86555e'	System	19 Aug 2020 23:17:55
User entered 'No (N)'	System	19 Aug 2020 23:17:55

FDA-CBER-2022-1614-1768568

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:17:53', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '70cce1e5-f0dc-4dd6-a0f6-d4bd7b86555e'	System	19 Aug 2020 23:17:55
User entered '19 Aug 2020 19:17'	System	19 Aug 2020 23:17:55

FDA-CBER-2022-1614-1768569

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '19 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768570

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '20 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768571

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 5'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:29:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768573

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:29:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768574

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:29:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:29:09
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768576

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:29:09
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768578

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '20 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768579

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '21 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768580

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 6'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:29:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:28:49', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'eff0d448-285c-4998-932f-cda24ebcb314'	System	21 Aug 2020 20:29:18
User entered 'Yes (Y)'	System	21 Aug 2020 20:29:18

FDA-CBER-2022-1614-1768582

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:29:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:01', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'eff0d448-285c-4998-932f-cda24ebcb314'	System	21 Aug 2020 20:29:18
User entered '98.3'	System	21 Aug 2020 20:29:18

FDA-CBER-2022-1614-1768583

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:29:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:08', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'eff0d448-285c-4998-932f-cda24ebcb314'	System	21 Aug 2020 20:29:18
User entered 'No (N)'	System	21 Aug 2020 20:29:18

FDA-CBER-2022-1614-1768584

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:15', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'eff0d448-285c-4998-932f-cda24ebcb314'	System	21 Aug 2020 20:29:18
User entered '21 Aug 2020 16:29'	System	21 Aug 2020 20:29:18

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '21 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768586

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '22 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768587

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 7'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768588

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:29:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:53:52', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '3f347bec-2d90-430a-a5ff-63051784b7d1'	System	23 Aug 2020 14:55:04
User entered 'Yes (Y)'	System	23 Aug 2020 14:55:04

FDA-CBER-2022-1614-1768589

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:29:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:54:37', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '3f347bec-2d90-430a-a5ff-63051784b7d1'	System	23 Aug 2020 14:55:04
User entered '98.3'	System	23 Aug 2020 14:55:04

FDA-CBER-2022-1614-1768590

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:29:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:54:42', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '3f347bec-2d90-430a-a5ff-63051784b7d1'	System	23 Aug 2020 14:55:04
User entered 'No (N)'	System	23 Aug 2020 14:55:04

FDA-CBER-2022-1614-1768591

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:54:58', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '3f347bec-2d90-430a-a5ff-63051784b7d1'	System	23 Aug 2020 14:55:04
User entered '23 Aug 2020 10:54'	System	23 Aug 2020 14:55:04

FDA-CBER-2022-1614-1768592

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '22 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768593

US3402382
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '23 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768594

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768595

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:48:02', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0f25afb-5ef6-4765-a8de-3bb243704d6d'	System	16 Aug 2020 17:48:44
User entered 'None (1)'	System	16 Aug 2020 17:48:44

FDA-CBER-2022-1614-1768596

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:48:36', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0f25afb-5ef6-4765-a8de-3bb243704d6d'	System	16 Aug 2020 17:48:44
User entered 'No (N)'	System	16 Aug 2020 17:48:44

FDA-CBER-2022-1614-1768597

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:48:23', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0f25afb-5ef6-4765-a8de-3bb243704d6d'	System	16 Aug 2020 17:48:44
User entered 'No (N)'	System	16 Aug 2020 17:48:44

FDA-CBER-2022-1614-1768598

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:48:30', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0f25afb-5ef6-4765-a8de-3bb243704d6d'	System	16 Aug 2020 17:48:44
User entered 'None (1)'	System	16 Aug 2020 17:48:44

FDA-CBER-2022-1614-1768599

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:48:41', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0f25afb-5ef6-4765-a8de-3bb243704d6d'	System	16 Aug 2020 17:48:44
User entered '16 Aug 2020 13:48'	System	16 Aug 2020 17:48:44

FDA-CBER-2022-1614-1768600

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '16 Aug 2020 13:33'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768601

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '16 Aug 2020 16:03'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768602

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 1, after vaccination (at home)'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:45:35', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c0723321-64cd-4cec-b641-0ecb948bafb6'	System	17 Aug 2020 01:46:33
User entered 'None (1)'	System	17 Aug 2020 01:46:33

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:45:45', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c0723321-64cd-4cec-b641-0ecb948bafb6'	System	17 Aug 2020 01:46:33
User entered 'No (N)'	System	17 Aug 2020 01:46:33

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:45:52', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c0723321-64cd-4cec-b641-0ecb948bafb6'	System	17 Aug 2020 01:46:33
User entered 'No (N)'	System	17 Aug 2020 01:46:33

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:46:18', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c0723321-64cd-4cec-b641-0ecb948bafb6'	System	17 Aug 2020 01:46:33
User entered 'None (1)'	System	17 Aug 2020 01:46:33

FDA-CBER-2022-1614-1768607

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:46:30', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c0723321-64cd-4cec-b641-0ecb948bafb6'	System	17 Aug 2020 01:46:33
User entered '16 Aug 2020 21:46'	System	17 Aug 2020 01:46:33

FDA-CBER-2022-1614-1768608

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '16 Aug 2020 16:58'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768609

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '17 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768610

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 2'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768611

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768613

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768615

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768616

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768618

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768620

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 3'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:24:31', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'e4c35dfb-4aca-4dd8-93fe-043c70fe9c6e'	System	18 Aug 2020 17:25:04
User entered 'None (1)'	System	18 Aug 2020 17:25:04

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:29:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:24:37', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'e4c35dfb-4aca-4dd8-93fe-043c70fe9c6e'	System	18 Aug 2020 17:25:04
User entered 'No (N)'	System	18 Aug 2020 17:25:04

FDA-CBER-2022-1614-1768623

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:29:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:24:40', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'e4c35dfb-4aca-4dd8-93fe-043c70fe9c6e'	System	18 Aug 2020 17:25:04
User entered 'No (N)'	System	18 Aug 2020 17:25:04

FDA-CBER-2022-1614-1768624

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:24:49', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'e4c35dfb-4aca-4dd8-93fe-043c70fe9c6e'	System	18 Aug 2020 17:25:04
User entered 'None (1)'	System	18 Aug 2020 17:25:04

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:25:01', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'e4c35dfb-4aca-4dd8-93fe-043c70fe9c6e'	System	18 Aug 2020 17:25:04
User entered '18 Aug 2020 13:25'	System	18 Aug 2020 17:25:04

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768627

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768628

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 4'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768629

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:18:05', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd6cebe28-fed4-4649-8cc5-c31ffa171106'	System	19 Aug 2020 23:18:36
User entered 'None (1)'	System	19 Aug 2020 23:18:36

FDA-CBER-2022-1614-1768630

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:29:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:18:12', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd6cebe28-fed4-4649-8cc5-c31ffa171106'	System	19 Aug 2020 23:18:36
User entered 'No (N)'	System	19 Aug 2020 23:18:36

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:29:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:18:18', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd6cebe28-fed4-4649-8cc5-c31ffa171106'	System	19 Aug 2020 23:18:36
User entered 'No (N)'	System	19 Aug 2020 23:18:36

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:18:25', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd6cebe28-fed4-4649-8cc5-c31ffa171106'	System	19 Aug 2020 23:18:36
User entered 'None (1)'	System	19 Aug 2020 23:18:36

FDA-CBER-2022-1614-1768633

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:18:34', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd6cebe28-fed4-4649-8cc5-c31ffa171106'	System	19 Aug 2020 23:18:36
User entered '19 Aug 2020 19:18'	System	19 Aug 2020 23:18:36

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '19 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768635

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '20 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768636

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 5'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768638

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768639

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768641

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768642

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768644

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '20 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768645

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '21 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768646

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 6'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768647

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:28:01', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd8eace2f-d4e6-4d08-a1f2-1c7888b73266'	System	21 Aug 2020 20:28:29
User entered 'None (1)'	System	21 Aug 2020 20:28:29

FDA-CBER-2022-1614-1768648

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:29:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:28:07', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd8eace2f-d4e6-4d08-a1f2-1c7888b73266'	System	21 Aug 2020 20:28:29
User entered 'No (N)'	System	21 Aug 2020 20:28:29

FDA-CBER-2022-1614-1768649

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:29:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:28:12', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd8eace2f-d4e6-4d08-a1f2-1c7888b73266'	System	21 Aug 2020 20:28:29
User entered 'No (N)'	System	21 Aug 2020 20:28:29

FDA-CBER-2022-1614-1768650

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:28:18', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd8eace2f-d4e6-4d08-a1f2-1c7888b73266'	System	21 Aug 2020 20:28:29
User entered 'None (1)'	System	21 Aug 2020 20:28:29

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:28:28', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd8eace2f-d4e6-4d08-a1f2-1c7888b73266'	System	21 Aug 2020 20:28:29
User entered '21 Aug 2020 16:28'	System	21 Aug 2020 20:28:29

FDA-CBER-2022-1614-1768652

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '21 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768653

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '22 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 7'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:55:12', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2a59c018-0871-4e34-84d9-2b11e799955c'	System	23 Aug 2020 14:55:45
User entered 'None (1)'	System	23 Aug 2020 14:55:45

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:29:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:55:18', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2a59c018-0871-4e34-84d9-2b11e799955c'	System	23 Aug 2020 14:55:45
User entered 'No (N)'	System	23 Aug 2020 14:55:45

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:29:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:55:25', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2a59c018-0871-4e34-84d9-2b11e799955c'	System	23 Aug 2020 14:55:45
User entered 'No (N)'	System	23 Aug 2020 14:55:45

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:55:32', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2a59c018-0871-4e34-84d9-2b11e799955c'	System	23 Aug 2020 14:55:45
User entered 'None (1)'	System	23 Aug 2020 14:55:45

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:55:40', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2a59c018-0871-4e34-84d9-2b11e799955c'	System	23 Aug 2020 14:55:45
User entered '23 Aug 2020 10:55'	System	23 Aug 2020 14:55:45

FDA-CBER-2022-1614-1768660

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '22 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768661

US3402382
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '23 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:49:07', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ef84477-85ec-45d1-964e-dd76c206c371'	System	16 Aug 2020 17:49:51
User entered 'None (0)'	System	16 Aug 2020 17:49:51

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:49:13', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ef84477-85ec-45d1-964e-dd76c206c371'	System	16 Aug 2020 17:49:51
User entered 'None (0)'	System	16 Aug 2020 17:49:51

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:49:19', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ef84477-85ec-45d1-964e-dd76c206c371'	System	16 Aug 2020 17:49:51
User entered 'None (0)'	System	16 Aug 2020 17:49:51

FDA-CBER-2022-1614-1768666

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:49:22', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ef84477-85ec-45d1-964e-dd76c206c371'	System	16 Aug 2020 17:49:51
User entered 'None (0)'	System	16 Aug 2020 17:49:51

FDA-CBER-2022-1614-1768667

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:49:26', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ef84477-85ec-45d1-964e-dd76c206c371'	System	16 Aug 2020 17:49:51
User entered 'None (0)'	System	16 Aug 2020 17:49:51

FDA-CBER-2022-1614-1768668

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:49:33', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ef84477-85ec-45d1-964e-dd76c206c371'	System	16 Aug 2020 17:49:51
User entered 'None (0)'	System	16 Aug 2020 17:49:51

FDA-CBER-2022-1614-1768669

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:49:42', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ef84477-85ec-45d1-964e-dd76c206c371'	System	16 Aug 2020 17:49:51
User entered 'No (N)'	System	16 Aug 2020 17:49:51

FDA-CBER-2022-1614-1768670

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:49:47', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ef84477-85ec-45d1-964e-dd76c206c371'	System	16 Aug 2020 17:49:51
User entered '16 Aug 2020 13:49'	System	16 Aug 2020 17:49:51

FDA-CBER-2022-1614-1768671

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '16 Aug 2020 13:33'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768672

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '16 Aug 2020 16:03'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768673

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 1, after vaccination (at home)'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:46:43', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '616c21e4-2974-4184-9e02-e74731e98aa9'	System	17 Aug 2020 01:47:42
User entered 'None (0)'	System	17 Aug 2020 01:47:42

FDA-CBER-2022-1614-1768675

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:46:49', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '616c21e4-2974-4184-9e02-e74731e98aa9'	System	17 Aug 2020 01:47:42
User entered 'None (0)'	System	17 Aug 2020 01:47:42

FDA-CBER-2022-1614-1768676

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:46:53', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '616c21e4-2974-4184-9e02-e74731e98aa9'	System	17 Aug 2020 01:47:42
User entered 'None (0)'	System	17 Aug 2020 01:47:42

FDA-CBER-2022-1614-1768677

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:46:58', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '616c21e4-2974-4184-9e02-e74731e98aa9'	System	17 Aug 2020 01:47:42
User entered 'None (0)'	System	17 Aug 2020 01:47:42

FDA-CBER-2022-1614-1768678

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:47:08', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '616c21e4-2974-4184-9e02-e74731e98aa9'	System	17 Aug 2020 01:47:42
User entered 'None (0)'	System	17 Aug 2020 01:47:42

FDA-CBER-2022-1614-1768679

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:47:14', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '616c21e4-2974-4184-9e02-e74731e98aa9'	System	17 Aug 2020 01:47:42
User entered 'None (0)'	System	17 Aug 2020 01:47:42

FDA-CBER-2022-1614-1768680

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:47:27', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '616c21e4-2974-4184-9e02-e74731e98aa9'	System	17 Aug 2020 01:47:42
User entered 'No (N)'	System	17 Aug 2020 01:47:42

FDA-CBER-2022-1614-1768681

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:47:40', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '616c21e4-2974-4184-9e02-e74731e98aa9'	System	17 Aug 2020 01:47:42
User entered '16 Aug 2020 21:47'	System	17 Aug 2020 01:47:42

FDA-CBER-2022-1614-1768682

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '16 Aug 2020 16:58'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768683

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '17 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768684

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 2'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768686

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768687

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768688

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768689

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768690

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768691

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768693

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768694

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768695

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 3'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768696

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:25:12', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7e6d6a56-7211-4927-bd93-8e3843cac5dd'	System	18 Aug 2020 17:26:07
User entered 'None (0)'	System	18 Aug 2020 17:26:07

FDA-CBER-2022-1614-1768697

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:25:27', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7e6d6a56-7211-4927-bd93-8e3843cac5dd'	System	18 Aug 2020 17:26:07
User entered 'No interference with activity (1)'	System	18 Aug 2020 17:26:07

FDA-CBER-2022-1614-1768698

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:25:35', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7e6d6a56-7211-4927-bd93-8e3843cac5dd'	System	18 Aug 2020 17:26:07
User entered 'No interference with activity (1)'	System	18 Aug 2020 17:26:07

FDA-CBER-2022-1614-1768699

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:25:44', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7e6d6a56-7211-4927-bd93-8e3843cac5dd'	System	18 Aug 2020 17:26:07
User entered 'No interference with activity (1)'	System	18 Aug 2020 17:26:07

FDA-CBER-2022-1614-1768700

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:25:48', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7e6d6a56-7211-4927-bd93-8e3843cac5dd'	System	18 Aug 2020 17:26:07
User entered 'None (0)'	System	18 Aug 2020 17:26:07

FDA-CBER-2022-1614-1768701

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:25:53', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7e6d6a56-7211-4927-bd93-8e3843cac5dd'	System	18 Aug 2020 17:26:07
User entered 'None (0)'	System	18 Aug 2020 17:26:07

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:25:58', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7e6d6a56-7211-4927-bd93-8e3843cac5dd'	System	18 Aug 2020 17:26:07
User entered 'No (N)'	System	18 Aug 2020 17:26:07

FDA-CBER-2022-1614-1768703

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:26:05', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7e6d6a56-7211-4927-bd93-8e3843cac5dd'	System	18 Aug 2020 17:26:07
User entered '18 Aug 2020 13:26'	System	18 Aug 2020 17:26:07

FDA-CBER-2022-1614-1768704

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768705

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768706

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 4'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768707

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:19:18', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '18d71477-6c55-430f-8f8f-df0f6d1654ff'	System	19 Aug 2020 23:20:11
User entered 'None (0)'	System	19 Aug 2020 23:20:11

FDA-CBER-2022-1614-1768708

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:19:29', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '18d71477-6c55-430f-8f8f-df0f6d1654ff'	System	19 Aug 2020 23:20:11
User entered 'None (0)'	System	19 Aug 2020 23:20:11

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:19:34', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '18d71477-6c55-430f-8f8f-df0f6d1654ff'	System	19 Aug 2020 23:20:11
User entered 'None (0)'	System	19 Aug 2020 23:20:11

FDA-CBER-2022-1614-1768710

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:19:46', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '18d71477-6c55-430f-8f8f-df0f6d1654ff'	System	19 Aug 2020 23:20:11
User entered 'None (0)'	System	19 Aug 2020 23:20:11

FDA-CBER-2022-1614-1768711

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:19:51', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '18d71477-6c55-430f-8f8f-df0f6d1654ff'	System	19 Aug 2020 23:20:11
User entered 'None (0)'	System	19 Aug 2020 23:20:11

FDA-CBER-2022-1614-1768712

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:19:58', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '18d71477-6c55-430f-8f8f-df0f6d1654ff'	System	19 Aug 2020 23:20:11
User entered 'None (0)'	System	19 Aug 2020 23:20:11

FDA-CBER-2022-1614-1768713

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:20:03', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '18d71477-6c55-430f-8f8f-df0f6d1654ff'	System	19 Aug 2020 23:20:11
User entered 'No (N)'	System	19 Aug 2020 23:20:11

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:20:09', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '18d71477-6c55-430f-8f8f-df0f6d1654ff'	System	19 Aug 2020 23:20:11
User entered '19 Aug 2020 19:20'	System	19 Aug 2020 23:20:11

FDA-CBER-2022-1614-1768715

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '19 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768716

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '20 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 5'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768719

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768720

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768721

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768723

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768724

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768726

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '20 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768727

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '21 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768728

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 6'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:25', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1e0e7715-17c1-4222-9551-240956d6f9ea'	System	21 Aug 2020 20:30:02
User entered 'None (0)'	System	21 Aug 2020 20:30:02

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:32', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1e0e7715-17c1-4222-9551-240956d6f9ea'	System	21 Aug 2020 20:30:02
User entered 'None (0)'	System	21 Aug 2020 20:30:02

FDA-CBER-2022-1614-1768731

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:36', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1e0e7715-17c1-4222-9551-240956d6f9ea'	System	21 Aug 2020 20:30:02
User entered 'None (0)'	System	21 Aug 2020 20:30:02

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:40', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1e0e7715-17c1-4222-9551-240956d6f9ea'	System	21 Aug 2020 20:30:02
User entered 'None (0)'	System	21 Aug 2020 20:30:02

FDA-CBER-2022-1614-1768733

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:44', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1e0e7715-17c1-4222-9551-240956d6f9ea'	System	21 Aug 2020 20:30:02
User entered 'None (0)'	System	21 Aug 2020 20:30:02

FDA-CBER-2022-1614-1768734

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:49', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1e0e7715-17c1-4222-9551-240956d6f9ea'	System	21 Aug 2020 20:30:02
User entered 'None (0)'	System	21 Aug 2020 20:30:02

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:54', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1e0e7715-17c1-4222-9551-240956d6f9ea'	System	21 Aug 2020 20:30:02
User entered 'No (N)'	System	21 Aug 2020 20:30:02

FDA-CBER-2022-1614-1768736

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:57', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1e0e7715-17c1-4222-9551-240956d6f9ea'	System	21 Aug 2020 20:30:02
User entered '21 Aug 2020 16:29'	System	21 Aug 2020 20:30:02

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '21 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768738

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '22 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768739

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 7'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:55:59', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0856158-ec98-4db3-8070-3e1a7b55ff79'	System	23 Aug 2020 14:57:01
User entered 'None (0)'	System	23 Aug 2020 14:57:01

FDA-CBER-2022-1614-1768741

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:56:07', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0856158-ec98-4db3-8070-3e1a7b55ff79'	System	23 Aug 2020 14:57:01
User entered 'Some interference with activity (2)'	System	23 Aug 2020 14:57:01

FDA-CBER-2022-1614-1768742

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:56:15', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0856158-ec98-4db3-8070-3e1a7b55ff79'	System	23 Aug 2020 14:57:01
User entered 'None (0)'	System	23 Aug 2020 14:57:01

FDA-CBER-2022-1614-1768743

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:56:21', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0856158-ec98-4db3-8070-3e1a7b55ff79'	System	23 Aug 2020 14:57:01
User entered 'None (0)'	System	23 Aug 2020 14:57:01

FDA-CBER-2022-1614-1768744

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:56:41', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0856158-ec98-4db3-8070-3e1a7b55ff79'	System	23 Aug 2020 14:57:01
User entered 'None (0)'	System	23 Aug 2020 14:57:01

FDA-CBER-2022-1614-1768745

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:56:48', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0856158-ec98-4db3-8070-3e1a7b55ff79'	System	23 Aug 2020 14:57:01
User entered 'None (0)'	System	23 Aug 2020 14:57:01

FDA-CBER-2022-1614-1768746

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:56:53', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0856158-ec98-4db3-8070-3e1a7b55ff79'	System	23 Aug 2020 14:57:01
User entered 'No (N)'	System	23 Aug 2020 14:57:01

FDA-CBER-2022-1614-1768747

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:56:58', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0856158-ec98-4db3-8070-3e1a7b55ff79'	System	23 Aug 2020 14:57:01
User entered '23 Aug 2020 10:56'	System	23 Aug 2020 14:57:01

FDA-CBER-2022-1614-1768748

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '22 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '23 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1768750

US3402382
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	23 Aug 2020 14:57:01
User entered 'Day 8'	System	23 Aug 2020 14:57:01

FDA-CBER-2022-1614-1768751

US3402382
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T23:15:09', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2459a4e8-c5d5-48b9-bc96-e8aabcbf5072'	System	24 Aug 2020 03:15:24
User entered 'No interference with activity (1)'	System	24 Aug 2020 03:15:24

FDA-CBER-2022-1614-1768752

US3402382
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T23:15:20', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2459a4e8-c5d5-48b9-bc96-e8aabcbf5072'	System	24 Aug 2020 03:15:24
User entered '23 Aug 2020 23:15'	System	24 Aug 2020 03:15:24

FDA-CBER-2022-1614-1768753

US3402382
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '23 Aug 2020 12:00'	System	23 Aug 2020 14:57:01

US3402382
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '24 Aug 2020 11:59'	System	23 Aug 2020 14:57:01

FDA-CBER-2022-1614-1768755

US3402382
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	23 Aug 2020 14:57:01
User entered 'Day 9'	System	23 Aug 2020 14:57:01

FDA-CBER-2022-1614-1768756

US3402382
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-24T19:22:27', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '8e9111dc-4ad6-4932-855d-938f406bb53f'	System	24 Aug 2020 23:22:34
User entered 'None (0)'	System	24 Aug 2020 23:22:34

FDA-CBER-2022-1614-1768757

US3402382
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-24T19:22:32', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '8e9111dc-4ad6-4932-855d-938f406bb53f'	System	24 Aug 2020 23:22:34
User entered '24 Aug 2020 19:22'	System	24 Aug 2020 23:22:34

US3402382
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 14:57:01

US3402382
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 14:57:01

US3402382
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	23 Aug 2020 14:57:01
User entered 'Day 8'	System	23 Aug 2020 14:57:01

FDA-CBER-2022-1614-1768761

US3402382
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T23:15:27', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '9dc854a7-2197-4b1c-b455-909796aff921'	System	24 Aug 2020 03:15:37
User entered 'No (N)'	System	24 Aug 2020 03:15:37

FDA-CBER-2022-1614-1768762

US3402382
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:29:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T23:15:34', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '9dc854a7-2197-4b1c-b455-909796aff921'	System	24 Aug 2020 03:15:37
User entered '23 Aug 2020 23:15'	System	24 Aug 2020 03:15:37

FDA-CBER-2022-1614-1768763

US3402382
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '23 Aug 2020 12:00'	System	23 Aug 2020 14:57:01

FDA-CBER-2022-1614-1768764

US3402382
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '24 Aug 2020 11:59'	System	23 Aug 2020 14:57:01

FDA-CBER-2022-1614-1768765

US3402382
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	23 Aug 2020 14:57:01
User entered 'Day 9'	System	23 Aug 2020 14:57:01

FDA-CBER-2022-1614-1768766

US3402382
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-24T19:22:41', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '088a4cdb-b744-4251-a17f-1853bb558181'	System	24 Aug 2020 23:22:50
User entered 'No (N)'	System	24 Aug 2020 23:22:50

FDA-CBER-2022-1614-1768767

US3402382
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 17:29:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-24T19:22:47', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '088a4cdb-b744-4251-a17f-1853bb558181'	System	24 Aug 2020 23:22:50
User entered '24 Aug 2020 19:22'	System	24 Aug 2020 23:22:50

FDA-CBER-2022-1614-1768768

US3402382
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 14:57:01

FDA-CBER-2022-1614-1768769

US3402382
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 14:57:01

FDA-CBER-2022-1614-1768770

US3402382
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	24 Aug 2020 20:07:53

FDA-CBER-2022-1614-1768771

US3402382
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '24 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	24 Aug 2020 20:07:53

US3402382
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4) (b) (4)	24 Aug 2020 20:07:53

FDA-CBER-2022-1614-1768773

US3402382
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Aug 2020 20:07:53

US3402382
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	24 Aug 2020 20:07:57

US3402382
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered '1'	System	24 Aug 2020 20:07:57

US3402382
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:28

US3402382
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
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)	11 Sep 2020 13:04:27
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 'date correct' (Site from System).	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:40
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	10 Sep 2020 13:15:28
User entered '16 Aug 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:28

US3402382
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:28

US3402382
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:28

FDA-CBER-2022-1614-1768780

US3402382
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:47

FDA-CBER-2022-1614-1768781

US3402382
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered '1'	System	10 Sep 2020 13:15:47

FDA-CBER-2022-1614-1768782

US3402382
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:16:04

US3402382
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '06 Sep 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 13:31:50
User entered '6 Sep 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:16:04

US3402382
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:16:04

US3402382
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:16:04

FDA-CBER-2022-1614-1768786

US3402382
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:16:10

US3402382
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered '1'	System	10 Sep 2020 13:16:10

FDA-CBER-2022-1614-1768788

US3402382
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:50

US3402382
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '14 Sep 2020'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:50

FDA-CBER-2022-1614-1768790

US3402382
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:50

US3402382
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered 'VISIT2'	System	14 Sep 2020 17:15:50

FDA-CBER-2022-1614-1768792

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768793

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '14 Sep 2020'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '11:30'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768796

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered '14 Sep 2020 11:30'	System	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768797

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '36.3' C	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768798

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768800

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '64'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered 'bpm'	System	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768802

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '18'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered 'breaths/min'	System	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768804

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '136'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768805

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered 'mmHg'	System	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768806

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:29
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 08:12:42
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NO CS/NCS THIS IS THE SUBJECTS CORRECT DIASTOLIC BLOOD PRESSURE' (Site from System).	Tammy Kohn (b) (4)	18 Sep 2020 13:37:07
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:59:08
User entered '58'	Traci Hull (b) (4)	14 Sep 2020 17:18:17

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered 'mmHg'	System	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768808

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768810

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '14 Sep 2020'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '12:35'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768812

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered '14 Sep 2020 12:35'	System	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768813

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '36.4' C	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768814

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768816

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '52'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768817

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered 'bpm'	System	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768818

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '18'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered 'breaths/min'	System	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768820

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '130'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768821

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered 'mmHg'	System	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768822

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '62'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768823

US3402382
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered 'mmHg'	System	14 Sep 2020 17:18:17

FDA-CBER-2022-1614-1768824

US3402382
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:29:09
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:23

US3402382
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:29:09
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '14 Sep 2020'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:23

FDA-CBER-2022-1614-1768826

US3402382
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	14 Sep 2020 16:12:18

US3402382
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered empty.	Tarin Gordon (b) (4) (b) (4)	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768828

US3402382
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
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)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered empty.	Tarin Gordon (b) (4) (b) (4)	14 Sep 2020 16:12:18

US3402382
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 16:12:18

US3402382
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '14 Sep 2020'	Tarin Gordon (b) (4) (b) (4)	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768831

US3402382
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '12:03'	Tarin Gordon (b) (4) (b) (4)	14 Sep 2020 16:12:18

US3402382
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered '14 Sep 2020 12:03'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768833

US3402382
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Left Arm (LEFT ARM)'	Tarin Gordon (b) (4) (b) (4)	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768834

US3402382
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered 'ONCE'	System	14 Sep 2020 16:12:18

US3402382
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768836

US3402382
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User closed query 'Per IMMUNO Lab Recon: GCL has a Unscheduled Lab with a collection date of 28AUG2020; however, there is no record in EDC with this date. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 17:47:00
Query 'Per IMMUNO Lab Recon: GCL has a Unscheduled Lab with a collection date of 28AUG2020; however, there is no record in EDC with this date. Please reconcile or clarify.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	06 Oct 2020 17:34:13
User opened query 'Per IMMUNO Lab Recon: GCL has a Unscheduled Lab with a collection date of 28AUG2020; however, there is no record in EDC with this date. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 08:52:07
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:44

US3402382
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '14 Sep 2020'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:44

FDA-CBER-2022-1614-1768838

US3402382
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '11:46'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:44

US3402382
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered '14 Sep 2020 11:46'	System	14 Sep 2020 17:18:44

US3402382
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 17:29:09
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:29
User closed query 'Per GCL Lab Reconciliation: Swab: response noted. However, please confirm if unscheduled lab kit was used for visit 2 day 29. since both visits have the same collection date.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 08:15:44
Query 'Per GCL Lab Reconciliation: Swab: response noted. However, please confirm if unscheduled lab kit was used for visit 2 day 29. since both visits have the same collection date.' answered with 'VISIT 2 DAY 29 KIT A WOULD HAVE BEEN USED NOT UNSCHEDULED.' (Site from DM).	Traci Hull (b) (4)	04 Nov 2020 15:10:14
User opened query 'Per GCL Lab Reconciliation: Swab: response noted. However, please confirm if unscheduled lab kit was used for visit 2 day 29. since both visits have the same collection date.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 14:48:45
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 14SEP2020 is reported under Unscheduled visit in PPD Central lab, however same date is reported under Visit 2 Day 29 in EDC. Please confirm the correct visit. else clarify ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 14:48:45
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 14SEP2020 is reported under Unscheduled visit in PPD Central lab, however same date is reported under Visit 2 Day 29 in EDC. Please confirm the correct visit. else clarify ' answered with 'This is correct as is' (Site from DM).	Jennifer Molstead (b) (4)	30 Oct 2020 14:00:55
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 14SEP2020 is reported under Unscheduled visit in PPD Central lab, however same date is reported under Visit 2 Day 29 in EDC. Please confirm the correct visit. else clarify ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:44:31
User entered '14 Sep 2020'	Traci Hull (b) (4)	14 Sep 2020 17:18:56

US3402382
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:29:09
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:56

FDA-CBER-2022-1614-1768842

US3402382
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:29:09
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:56

US3402382
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:29:09
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '11:43'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:56

FDA-CBER-2022-1614-1768844

US3402382
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:29:09
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered '14 Sep 2020 11:43'	System	14 Sep 2020 17:18:56

US3402382
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:29:09
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:56

FDA-CBER-2022-1614-1768846

US3402382
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:29:09
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:56

US3402382
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:29:09
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:56

FDA-CBER-2022-1614-1768848

US3402382
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:29:09
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered empty.	System	14 Sep 2020 17:18:56

US3402382
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:19:00

US3402382
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered '1'	System	14 Sep 2020 17:19:00

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768852

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:35:45', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7204a7b9-2912-48fc-abdc-d2fee24c0577'	System	14 Sep 2020 16:35:58
User entered 'Yes (Y)'	System	14 Sep 2020 16:35:58

FDA-CBER-2022-1614-1768853

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:35:30', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7204a7b9-2912-48fc-abdc-d2fee24c0577'	System	14 Sep 2020 16:35:58
User entered '97.4'	System	14 Sep 2020 16:35:58

FDA-CBER-2022-1614-1768854

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:35:38', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7204a7b9-2912-48fc-abdc-d2fee24c0577'	System	14 Sep 2020 16:35:58
User entered 'No (N)'	System	14 Sep 2020 16:35:58

FDA-CBER-2022-1614-1768855

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:35:55', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7204a7b9-2912-48fc-abdc-d2fee24c0577'	System	14 Sep 2020 16:35:58
User entered '14 Sep 2020 12:35'	System	14 Sep 2020 16:35:58

FDA-CBER-2022-1614-1768856

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '14 Sep 2020 12:23'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '14 Sep 2020 14:53'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768858

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768860

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768861

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768864

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768865

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '14 Sep 2020 15:48'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 2'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768868

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:29:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768869

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:29:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768870

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:29:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:29:09
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768872

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:29:09
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768874

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 3'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768877

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:29:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768878

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:29:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768879

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:29:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768880

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:29:09
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:29:09
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768882

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768883

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768885

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 4'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768886

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:29:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768887

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:29:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768888

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:29:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768889

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:29:09
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768890

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:29:09
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768891

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768892

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768894

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 5'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768895

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:29:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768896

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:29:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768897

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:29:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:29:09
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768899

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:29:09
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768900

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768901

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768902

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768903

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 6'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768904

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:29:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768905

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:29:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768906

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:29:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:29:09
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768908

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:29:09
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768909

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768910

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768911

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 7'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768913

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:29:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768914

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:29:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768915

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:29:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:29:09
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768917

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:29:09
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768919

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:36:08', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c2729988-399e-4bc0-ab9a-6c1ffddbd3c0'	System	14 Sep 2020 16:36:44
User entered 'None (1)'	System	14 Sep 2020 16:36:44

FDA-CBER-2022-1614-1768923

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:36:12', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c2729988-399e-4bc0-ab9a-6c1ffddbd3c0'	System	14 Sep 2020 16:36:44
User entered 'No (N)'	System	14 Sep 2020 16:36:44

FDA-CBER-2022-1614-1768924

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:36:23', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c2729988-399e-4bc0-ab9a-6c1ffddbd3c0'	System	14 Sep 2020 16:36:44
User entered 'No (N)'	System	14 Sep 2020 16:36:44

FDA-CBER-2022-1614-1768925

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:36:30', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c2729988-399e-4bc0-ab9a-6c1ffddbd3c0'	System	14 Sep 2020 16:36:44
User entered 'None (1)'	System	14 Sep 2020 16:36:44

FDA-CBER-2022-1614-1768926

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:36:40', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c2729988-399e-4bc0-ab9a-6c1ffddbd3c0'	System	14 Sep 2020 16:36:44
User entered '14 Sep 2020 12:36'	System	14 Sep 2020 16:36:44

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '14 Sep 2020 12:23'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768928

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '14 Sep 2020 14:53'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768931

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768932

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768933

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768934

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768935

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768936

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768937

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '14 Sep 2020 15:48'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768938

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768939

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 2'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768940

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768941

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768942

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768943

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768944

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768945

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768946

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768947

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768948

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 3'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768950

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768951

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:29:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768952

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768953

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:29:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768954

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768955

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768956

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768957

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768958

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768959

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 4'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768960

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768961

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:29:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768962

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768963

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:29:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768964

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768965

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768966

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768967

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768968

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768969

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 5'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768970

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768971

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768973

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768974

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768975

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768977

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768978

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768979

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 6'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768981

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:29:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768982

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768983

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:29:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768984

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768985

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768986

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768987

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768988

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 7'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768991

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:29:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768993

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:29:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768994

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768995

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1768996

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:29:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1768997

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1768998

US3402382
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:36:54', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'b0889c7b-c5d6-4321-8651-b7cbf1261355'	System	14 Sep 2020 16:37:44
User entered 'None (0)'	System	14 Sep 2020 16:37:44

FDA-CBER-2022-1614-1769001

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:37:03', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'b0889c7b-c5d6-4321-8651-b7cbf1261355'	System	14 Sep 2020 16:37:44
User entered 'No interference with activity (1)'	System	14 Sep 2020 16:37:44

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:37:09', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'b0889c7b-c5d6-4321-8651-b7cbf1261355'	System	14 Sep 2020 16:37:44
User entered 'None (0)'	System	14 Sep 2020 16:37:44

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:37:15', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'b0889c7b-c5d6-4321-8651-b7cbf1261355'	System	14 Sep 2020 16:37:44
User entered 'None (0)'	System	14 Sep 2020 16:37:44

FDA-CBER-2022-1614-1769004

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:37:20', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'b0889c7b-c5d6-4321-8651-b7cbf1261355'	System	14 Sep 2020 16:37:44
User entered 'None (0)'	System	14 Sep 2020 16:37:44

FDA-CBER-2022-1614-1769005

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:37:24', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'b0889c7b-c5d6-4321-8651-b7cbf1261355'	System	14 Sep 2020 16:37:44
User entered 'None (0)'	System	14 Sep 2020 16:37:44

FDA-CBER-2022-1614-1769006

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:37:36', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'b0889c7b-c5d6-4321-8651-b7cbf1261355'	System	14 Sep 2020 16:37:44
User entered 'No (N)'	System	14 Sep 2020 16:37:44

FDA-CBER-2022-1614-1769007

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:37:40', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'b0889c7b-c5d6-4321-8651-b7cbf1261355'	System	14 Sep 2020 16:37:44
User entered '14 Sep 2020 12:37'	System	14 Sep 2020 16:37:44

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '14 Sep 2020 12:23'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1769009

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '14 Sep 2020 14:53'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1769010

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769012

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769013

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769014

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769016

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769017

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1769018

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769019

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '14 Sep 2020 15:48'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1769020

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

FDA-CBER-2022-1614-1769021

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 2'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769023

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769024

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769025

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769027

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769028

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769030

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 3'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769034

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769035

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769036

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769038

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769039

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769041

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 4'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769045

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769046

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769047

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769049

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769050

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

FDA-CBER-2022-1614-1769051

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769052

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 5'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769056

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769057

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769058

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769061

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769063

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 6'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769067

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769068

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769069

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769071

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769072

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769074

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 7'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769078

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769079

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769080

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769081

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769082

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769083

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
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 04:48:48

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48

FDA-CBER-2022-1614-1769085

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:29:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	21 Sep 2020 18:35:31

US3402382
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '21 Sep 2020'	Traci Hull (b) (4) (b) (4)	21 Sep 2020 18:35:31

US3402382
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	21 Sep 2020 18:35:31

US3402382
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered empty.	Traci Hull (b) (4) (b) (4)	21 Sep 2020 18:35:31

US3402382
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	21 Sep 2020 18:35:36

US3402382
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered '1'	System	21 Sep 2020 18:35:36

US3402382
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Sep 2020 19:52:31

US3402382
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '28 Sep 2020'	Traci Hull (b) (4) (b) (4)	29 Sep 2020 19:52:31

US3402382
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	29 Sep 2020 19:52:31

US3402382
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered empty.	Traci Hull (b) (4) (b) (4)	29 Sep 2020 19:52:31

FDA-CBER-2022-1614-1769097

US3402382
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Sep 2020 19:52:35

US3402382
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered '1'	System	29 Sep 2020 19:52:35

US3402382
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:31:19

US3402382
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '05 Oct 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 13:32:46
User entered '5 Oct 2020'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:31:19

US3402382
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:31:19

US3402382
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered empty.	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:31:19

FDA-CBER-2022-1614-1769103

US3402382
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:31:23

US3402382
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered '1'	System	12 Oct 2020 17:31:23

FDA-CBER-2022-1614-1769105

US3402382
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:31:34

US3402382
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '12 Oct 2020'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:31:34

FDA-CBER-2022-1614-1769107

US3402382
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:31:34

US3402382
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered 'VISIT3'	System	12 Oct 2020 17:31:34

FDA-CBER-2022-1614-1769109

US3402382
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:11

US3402382
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '12 Oct 2020'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:11

US3402382
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '12:32'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:11

FDA-CBER-2022-1614-1769112

US3402382
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered '12 Oct 2020 12:32'	System	12 Oct 2020 17:32:11

FDA-CBER-2022-1614-1769113

US3402382
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '97.1' F	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:11

US3402382
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:11

US3402382
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered empty.	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:11

US3402382
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '63'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:11

US3402382
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered 'bpm'	System	12 Oct 2020 17:32:11

FDA-CBER-2022-1614-1769118

US3402382
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '16'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:11

US3402382
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered 'breaths/min'	System	12 Oct 2020 17:32:11

FDA-CBER-2022-1614-1769120

US3402382
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '108'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:11

FDA-CBER-2022-1614-1769121

US3402382
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered 'mmHg'	System	12 Oct 2020 17:32:11

FDA-CBER-2022-1614-1769122

US3402382
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '75'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:11

FDA-CBER-2022-1614-1769123

US3402382
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered 'mmHg'	System	12 Oct 2020 17:32:11

FDA-CBER-2022-1614-1769124

US3402382
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16

FDA-CBER-2022-1614-1769125

US3402382
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16

FDA-CBER-2022-1614-1769126

US3402382
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:29:09
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:19

US3402382
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:29:09
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered empty.	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:19

US3402382
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:31

US3402382
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '12 Oct 2020'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:31

US3402382
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered '12:35'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:31

FDA-CBER-2022-1614-1769131

US3402382
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered '12 Oct 2020 12:35'	System	12 Oct 2020 17:32:31

US3402382
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:24:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:36

US3402382
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:16
User entered '1'	System	12 Oct 2020 17:32:36

FDA-CBER-2022-1614-1769134

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 64'	System	16 Aug 2020 17:17:49

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-16T08:25:10', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '29ff1126-e938-4b91-b767-549b43fbf1fe'	System	16 Oct 2020 12:25:37
User entered 'No (N)'	System	16 Oct 2020 12:25:37

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with 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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-16T08:25:16', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '29ff1126-e938-4b91-b767-549b43fbf1fe'	System	16 Oct 2020 12:25:37
User entered 'No (N)'	System	16 Oct 2020 12:25:37

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-16T08:25:33', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '29ff1126-e938-4b91-b767-549b43fbf1fe'	System	16 Oct 2020 12:25:37
User entered '16 Oct 2020 08:25:33'	System	16 Oct 2020 12:25:37

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered '16 Oct 2020 00:01'	System	16 Aug 2020 17:17:49

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered '20 Oct 2020 23:59'	System	16 Aug 2020 17:17:49

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 71'	System	16 Aug 2020 17:17:49

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-23T11:08:23', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1599dade-793a-4dee-b434-0bac5787adc7'	System	23 Oct 2020 15:08:43
User entered 'No (N)'	System	23 Oct 2020 15:08:43

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with 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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-23T11:08:30', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1599dade-793a-4dee-b434-0bac5787adc7'	System	23 Oct 2020 15:08:43
User entered 'No (N)'	System	23 Oct 2020 15:08:43

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-23T11:08:41', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1599dade-793a-4dee-b434-0bac5787adc7'	System	23 Oct 2020 15:08:43
User entered '23 Oct 2020 11:08:41'	System	23 Oct 2020 15:08:43

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered '23 Oct 2020 00:01'	System	16 Aug 2020 17:17:49

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered '27 Oct 2020 23:59'	System	16 Aug 2020 17:17:49

FDA-CBER-2022-1614-1769146

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 78'	System	16 Aug 2020 17:17:49

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

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 04:48:48
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 13:21:14
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'No AE or SAE, Subject checked yes because he had gotten out of the hospital which has already been recorded ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	02 Dec 2020 13:10:21
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 11:10:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-31T11:06:27', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '336840dd-3748-443d-bf46-a3643e70a549'	System	31 Oct 2020 15:07:39
User entered 'Yes (Y)'	System	31 Oct 2020 15:07:39

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with 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 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-31T11:06:34', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '336840dd-3748-443d-bf46-a3643e70a549'	System	31 Oct 2020 15:07:39
User entered 'No (N)'	System	31 Oct 2020 15:07:39

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-31T11:06:46', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '336840dd-3748-443d-bf46-a3643e70a549'	System	31 Oct 2020 15:07:39
User entered 'No (N)'	System	31 Oct 2020 15:07:39

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-31T11:06:55', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '336840dd-3748-443d-bf46-a3643e70a549'	System	31 Oct 2020 15:07:39
User entered 'Yes (Y)'	System	31 Oct 2020 15:07:39

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-31T11:07:17', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '336840dd-3748-443d-bf46-a3643e70a549'	System	31 Oct 2020 15:07:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Oct 2020 15:07:39

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-31T11:07:29', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '336840dd-3748-443d-bf46-a3643e70a549'	System	31 Oct 2020 15:07:39
User entered '31 Oct 2020 11:07:29'	System	31 Oct 2020 15:07:39

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered '30 Oct 2020 00:01'	System	16 Aug 2020 17:17:49

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:48
Data entry locked.	System	16 Aug 2020 17:17:49
User entered '03 Nov 2020 23:59'	System	16 Aug 2020 17:17:49

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 92'	System	16 Aug 2020 17:17:49

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

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)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with 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)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Please 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)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

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)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Please 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)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

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)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Please 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)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29
Data entry locked.	System	16 Aug 2020 17:17:49
User entered '13 Nov 2020 00:01'	System	16 Aug 2020 17:17:49

US3402382
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:29
Data entry locked.	System	16 Aug 2020 17:17:49
User entered '17 Nov 2020 23:59'	System	16 Aug 2020 17:17:49

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-11-19T12:20:30', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '27d97114-8583-4367-95c6-f5e6f3791bd8'	System	19 Nov 2020 17:20:45
User entered 'No (N)'	System	19 Nov 2020 17:20:45

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-11-19T12:20:34', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '27d97114-8583-4367-95c6-f5e6f3791bd8'	System	19 Nov 2020 17:20:45
User entered 'No (N)'	System	19 Nov 2020 17:20:45

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-11-19T12:20:42', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '27d97114-8583-4367-95c6-f5e6f3791bd8'	System	19 Nov 2020 17:20:45
User entered '19 Nov 2020 12:20:42'	System	19 Nov 2020 17:20:45

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '17 Nov 2020 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '21 Nov 2020 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-11-24T07:50:36', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'bfa4db36-22f9-454e-a66e-29498ff42a45'	System	24 Nov 2020 12:51:08
User entered 'No (N)'	System	24 Nov 2020 12:51:08

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-11-24T07:50:55', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'bfa4db36-22f9-454e-a66e-29498ff42a45'	System	24 Nov 2020 12:51:08
User entered 'No (N)'	System	24 Nov 2020 12:51:08

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-11-24T07:51:05', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'bfa4db36-22f9-454e-a66e-29498ff42a45'	System	24 Nov 2020 12:51:08
User entered '24 Nov 2020 07:51:05'	System	24 Nov 2020 12:51:08

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '24 Nov 2020 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '28 Nov 2020 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-12-01T11:27:53', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c3d9d7b7-d9ef-43bb-a6cf-c89d51a05e51'	System	01 Dec 2020 16:28:08
User entered 'No (N)'	System	01 Dec 2020 16:28:08

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-12-01T11:28:01', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c3d9d7b7-d9ef-43bb-a6cf-c89d51a05e51'	System	01 Dec 2020 16:28:08
User entered 'No (N)'	System	01 Dec 2020 16:28:08

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-12-01T11:28:06', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c3d9d7b7-d9ef-43bb-a6cf-c89d51a05e51'	System	01 Dec 2020 16:28:08
User entered '01 Dec 2020 11:28:06'	System	01 Dec 2020 16:28:08

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '01 Dec 2020 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '05 Dec 2020 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-12-08T09:48:34', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '4b129340-0a4d-44f8-ac9c-019fc7390cb2'	System	08 Dec 2020 14:48:51
User entered 'No (N)'	System	08 Dec 2020 14:48:51

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-12-08T09:48:37', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '4b129340-0a4d-44f8-ac9c-019fc7390cb2'	System	08 Dec 2020 14:48:51
User entered 'No (N)'	System	08 Dec 2020 14:48:51

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-12-08T09:48:47', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '4b129340-0a4d-44f8-ac9c-019fc7390cb2'	System	08 Dec 2020 14:48:51
User entered '08 Dec 2020 09:48:47'	System	08 Dec 2020 14:48:51

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '08 Dec 2020 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '12 Dec 2020 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-12-15T09:36:53', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '4c7f2ef1-9582-44b3-9328-8e045c4e8218'	System	15 Dec 2020 14:37:12
User entered 'No (N)'	System	15 Dec 2020 14:37:12

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-12-15T09:36:59', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '4c7f2ef1-9582-44b3-9328-8e045c4e8218'	System	15 Dec 2020 14:37:12
User entered 'No (N)'	System	15 Dec 2020 14:37:12

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-12-15T09:37:10', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '4c7f2ef1-9582-44b3-9328-8e045c4e8218'	System	15 Dec 2020 14:37:12
User entered '15 Dec 2020 09:37:10'	System	15 Dec 2020 14:37:12

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '15 Dec 2020 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '19 Dec 2020 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-12-22T00:32:25', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '6730f0ed-4b40-4e22-8dc8-8ad7ae22b23b'	System	22 Dec 2020 05:32:43
User entered 'No (N)'	System	22 Dec 2020 05:32:43

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-12-22T00:32:32', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '6730f0ed-4b40-4e22-8dc8-8ad7ae22b23b'	System	22 Dec 2020 05:32:43
User entered 'No (N)'	System	22 Dec 2020 05:32:43

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-12-22T00:32:39', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '6730f0ed-4b40-4e22-8dc8-8ad7ae22b23b'	System	22 Dec 2020 05:32:43
User entered '22 Dec 2020 00:32:39'	System	22 Dec 2020 05:32:43

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '22 Dec 2020 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '26 Dec 2020 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-12-29T06:52:47', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c3116e91-d616-41f5-82d8-390a3287db08'	System	29 Dec 2020 11:53:04
User entered 'No (N)'	System	29 Dec 2020 11:53:04

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-12-29T06:52:53', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c3116e91-d616-41f5-82d8-390a3287db08'	System	29 Dec 2020 11:53:04
User entered 'No (N)'	System	29 Dec 2020 11:53:04

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-12-29T06:53:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c3116e91-d616-41f5-82d8-390a3287db08'	System	29 Dec 2020 11:53:04
User entered '29 Dec 2020 06:53:00'	System	29 Dec 2020 11:53:04

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '29 Dec 2020 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '02 Jan 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-01-05T00:22:46', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '93284d95-9b02-4d94-931c-19cf62651cbf'	System	05 Jan 2021 05:23:03
User entered 'No (N)'	System	05 Jan 2021 05:23:03

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-01-05T00:22:52', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '93284d95-9b02-4d94-931c-19cf62651cbf'	System	05 Jan 2021 05:23:03
User entered 'No (N)'	System	05 Jan 2021 05:23:03

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-01-05T00:23:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '93284d95-9b02-4d94-931c-19cf62651cbf'	System	05 Jan 2021 05:23:03
User entered '05 Jan 2021 00:23:00'	System	05 Jan 2021 05:23:03

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '05 Jan 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '09 Jan 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-01-12T18:50:41', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '8fa1b342-e93d-4b15-a371-158e4885089e'	System	12 Jan 2021 23:50:53
User entered 'No (N)'	System	12 Jan 2021 23:50:53

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-01-12T18:50:19', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '8fa1b342-e93d-4b15-a371-158e4885089e'	System	12 Jan 2021 23:50:53
User entered 'No (N)'	System	12 Jan 2021 23:50:53

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-01-12T18:50:51', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '8fa1b342-e93d-4b15-a371-158e4885089e'	System	12 Jan 2021 23:50:53
User entered '12 Jan 2021 18:50:51'	System	12 Jan 2021 23:50:53

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '12 Jan 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '16 Jan 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-01-19T17:37:55', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd847c334-cef9-44c4-82aa-97498da9cc56'	System	19 Jan 2021 22:38:29
User entered 'No (N)'	System	19 Jan 2021 22:38:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-01-19T17:38:02', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd847c334-cef9-44c4-82aa-97498da9cc56'	System	19 Jan 2021 22:38:29
User entered 'No (N)'	System	19 Jan 2021 22:38:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-01-19T17:38:24', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd847c334-cef9-44c4-82aa-97498da9cc56'	System	19 Jan 2021 22:38:29
User entered '19 Jan 2021 17:38:24'	System	19 Jan 2021 22:38:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '19 Jan 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '23 Jan 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-01-27T00:05:17', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '037dcc06-f3e8-4dc3-a9ef-106a1267907e'	System	27 Jan 2021 05:05:40
User entered 'No (N)'	System	27 Jan 2021 05:05:40

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-01-27T00:05:26', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '037dcc06-f3e8-4dc3-a9ef-106a1267907e'	System	27 Jan 2021 05:05:40
User entered 'No (N)'	System	27 Jan 2021 05:05:40

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-01-27T00:05:34', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '037dcc06-f3e8-4dc3-a9ef-106a1267907e'	System	27 Jan 2021 05:05:40
User entered '27 Jan 2021 00:05:34'	System	27 Jan 2021 05:05:40

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '26 Jan 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '30 Jan 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-02-05T23:52:34', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '85291f97-9b92-497a-8ffe-503043ddfbc7'	System	06 Feb 2021 04:52:50
User entered 'No (N)'	System	06 Feb 2021 04:52:50

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-02-05T23:52:37', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '85291f97-9b92-497a-8ffe-503043ddfbc7'	System	06 Feb 2021 04:52:50
User entered 'No (N)'	System	06 Feb 2021 04:52:50

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-02-05T23:52:43', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '85291f97-9b92-497a-8ffe-503043ddfbc7'	System	06 Feb 2021 04:52:50
User entered '05 Feb 2021 23:52:43'	System	06 Feb 2021 04:52:50

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '02 Feb 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '06 Feb 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-02-10T20:57:18', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'a731c0be-5f0f-429c-b3e0-e9da8868f9c8'	System	11 Feb 2021 01:57:33
User entered 'No (N)'	System	11 Feb 2021 01:57:33

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-02-10T20:57:21', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'a731c0be-5f0f-429c-b3e0-e9da8868f9c8'	System	11 Feb 2021 01:57:33
User entered 'No (N)'	System	11 Feb 2021 01:57:33

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-02-10T20:57:28', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'a731c0be-5f0f-429c-b3e0-e9da8868f9c8'	System	11 Feb 2021 01:57:33
User entered '10 Feb 2021 20:57:28'	System	11 Feb 2021 01:57:33

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '09 Feb 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '13 Feb 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-02-16T00:13:01', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '0d239ab6-1934-4e47-9263-05c2098da19d'	System	16 Feb 2021 05:13:13
User entered 'No (N)'	System	16 Feb 2021 05:13:13

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-02-16T00:13:06', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '0d239ab6-1934-4e47-9263-05c2098da19d'	System	16 Feb 2021 05:13:13
User entered 'No (N)'	System	16 Feb 2021 05:13:13

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-02-16T00:13:11', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '0d239ab6-1934-4e47-9263-05c2098da19d'	System	16 Feb 2021 05:13:13
User entered '16 Feb 2021 00:13:11'	System	16 Feb 2021 05:13:13

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '16 Feb 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '20 Feb 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-02-23T00:02:32-05:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2447dbe9-51b5-40e0-8237-50fc41656a75'	System	23 Feb 2021 05:03:32
User entered 'No (N)'	System	23 Feb 2021 05:03:32

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-02-23T00:02:38-05:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2447dbe9-51b5-40e0-8237-50fc41656a75'	System	23 Feb 2021 05:03:32
User entered 'No (N)'	System	23 Feb 2021 05:03:32

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-02-23T00:02:46-05:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2447dbe9-51b5-40e0-8237-50fc41656a75'	System	23 Feb 2021 05:03:32
User entered '23 Feb 2021 05:02:46'	System	23 Feb 2021 05:03:32

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '23 Feb 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '27 Feb 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-03-02T08:54:32-05:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '81343d20-d024-4a0c-873b-95cc873b8007'	System	02 Mar 2021 13:54:47
User entered 'No (N)'	System	02 Mar 2021 13:54:47

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-03-02T08:54:35-05:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '81343d20-d024-4a0c-873b-95cc873b8007'	System	02 Mar 2021 13:54:47
User entered 'No (N)'	System	02 Mar 2021 13:54:47

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-03-02T08:54:43-05:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '81343d20-d024-4a0c-873b-95cc873b8007'	System	02 Mar 2021 13:54:47
User entered '02 Mar 2021 08:54:43'	System	02 Mar 2021 13:54:47

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '02 Mar 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '06 Mar 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-03-09T11:16:52-05:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1a3c4f6d-7b37-4afb-9748-0866829f5156'	System	09 Mar 2021 16:17:05
User entered 'No (N)'	System	09 Mar 2021 16:17:05

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-03-09T11:16:56-05:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1a3c4f6d-7b37-4afb-9748-0866829f5156'	System	09 Mar 2021 16:17:05
User entered 'No (N)'	System	09 Mar 2021 16:17:05

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-03-09T11:17:01-05:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1a3c4f6d-7b37-4afb-9748-0866829f5156'	System	09 Mar 2021 16:17:05
User entered '09 Mar 2021 11:17:01'	System	09 Mar 2021 16:17:05

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '09 Mar 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '13 Mar 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-03-16T10:49:16-04:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7d70dbd4-8b33-4dc0-8333-348e93d89bbf'	System	16 Mar 2021 14:49:34
User entered 'No (N)'	System	16 Mar 2021 14:49:34

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-03-16T10:49:26-04:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7d70dbd4-8b33-4dc0-8333-348e93d89bbf'	System	16 Mar 2021 14:49:34
User entered 'No (N)'	System	16 Mar 2021 14:49:34

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-03-16T10:49:30-04:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7d70dbd4-8b33-4dc0-8333-348e93d89bbf'	System	16 Mar 2021 14:49:34
User entered '16 Mar 2021 10:49:30'	System	16 Mar 2021 14:49:34

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '16 Mar 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '20 Mar 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-03-23T23:39:12-04:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '6299677f-39a8-4e1f-8983-b3abeca403ca'	System	24 Mar 2021 03:39:32
User entered 'No (N)'	System	24 Mar 2021 03:39:32

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-03-23T23:39:15-04:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '6299677f-39a8-4e1f-8983-b3abeca403ca'	System	24 Mar 2021 03:39:32
User entered 'No (N)'	System	24 Mar 2021 03:39:32

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-03-23T23:39:26-04:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '6299677f-39a8-4e1f-8983-b3abeca403ca'	System	24 Mar 2021 03:39:32
User entered '23 Mar 2021 23:39:26'	System	24 Mar 2021 03:39:32

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '23 Mar 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '27 Mar 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-03-31T23:59:29-04:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '35c04c55-6ab3-4561-b921-bd93c0da06df'	System	01 Apr 2021 03:59:42
User entered 'No (N)'	System	01 Apr 2021 03:59:42

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-03-31T23:59:32-04:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '35c04c55-6ab3-4561-b921-bd93c0da06df'	System	01 Apr 2021 03:59:42
User entered 'No (N)'	System	01 Apr 2021 03:59:42

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-03-31T23:59:39-04:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '35c04c55-6ab3-4561-b921-bd93c0da06df'	System	01 Apr 2021 03:59:42
User entered '31 Mar 2021 23:59:39'	System	01 Apr 2021 03:59:42

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '30 Mar 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '03 Apr 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-04-06T00:38:52-04:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '388dba55-9669-4a0f-bf31-23b3ce435ab1'	System	06 Apr 2021 04:39:20
User entered 'No (N)'	System	06 Apr 2021 04:39:20

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-04-06T00:39:07-04:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '388dba55-9669-4a0f-bf31-23b3ce435ab1'	System	06 Apr 2021 04:39:20
User entered 'No (N)'	System	06 Apr 2021 04:39:20

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-04-06T00:39:18-04:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '388dba55-9669-4a0f-bf31-23b3ce435ab1'	System	06 Apr 2021 04:39:20
User entered '06 Apr 2021 00:39:18'	System	06 Apr 2021 04:39:20

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '06 Apr 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '10 Apr 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '13 Apr 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '17 Apr 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-04-20T19:08:58-04:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7737542e-74e3-4615-b36f-030ae1f530a6'	System	20 Apr 2021 23:09:22
User entered 'No (N)'	System	20 Apr 2021 23:09:22

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-04-20T19:09:06-04:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7737542e-74e3-4615-b36f-030ae1f530a6'	System	20 Apr 2021 23:09:22
User entered 'No (N)'	System	20 Apr 2021 23:09:22

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-04-20T19:09:15-04:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7737542e-74e3-4615-b36f-030ae1f530a6'	System	20 Apr 2021 23:09:22
User entered '20 Apr 2021 19:09:15'	System	20 Apr 2021 23:09:22

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '20 Apr 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '24 Apr 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-05-01T17:07:36-04:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd61b4c6e-e541-4477-91fe-f2528f3eb006'	System	01 May 2021 21:07:58
User entered 'No (N)'	System	01 May 2021 21:07:58

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-05-01T17:07:42-04:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd61b4c6e-e541-4477-91fe-f2528f3eb006'	System	01 May 2021 21:07:58
User entered 'No (N)'	System	01 May 2021 21:07:58

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-05-01T17:07:55-04:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd61b4c6e-e541-4477-91fe-f2528f3eb006'	System	01 May 2021 21:07:58
User entered '01 May 2021 17:07:55'	System	01 May 2021 21:07:58

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '27 Apr 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '01 May 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '04 May 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '08 May 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '11 May 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '15 May 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '18 May 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '22 May 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '25 May 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '29 May 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '01 Jun 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '05 Jun 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '08 Jun 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '12 Jun 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '15 Jun 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '19 Jun 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '22 Jun 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '26 Jun 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '29 Jun 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '03 Jul 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '06 Jul 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '10 Jul 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '13 Jul 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '17 Jul 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '20 Jul 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '24 Jul 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '27 Jul 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '31 Jul 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '03 Aug 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '07 Aug 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '10 Aug 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '14 Aug 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '17 Aug 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '21 Aug 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '24 Aug 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '28 Aug 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '31 Aug 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '04 Sep 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '07 Sep 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '11 Sep 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '14 Sep 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '18 Sep 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '21 Sep 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '25 Sep 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '28 Sep 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '02 Oct 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '05 Oct 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '09 Oct 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '12 Oct 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '16 Oct 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '19 Oct 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '23 Oct 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '26 Oct 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '30 Oct 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '02 Nov 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '06 Nov 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '09 Nov 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '13 Nov 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '16 Nov 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '20 Nov 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '23 Nov 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '27 Nov 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '30 Nov 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '04 Dec 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '07 Dec 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '11 Dec 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '14 Dec 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '18 Dec 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '21 Dec 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '25 Dec 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '28 Dec 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '01 Jan 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '04 Jan 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '08 Jan 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '11 Jan 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '15 Jan 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '18 Jan 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '22 Jan 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '25 Jan 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '29 Jan 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '01 Feb 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '05 Feb 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '08 Feb 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '12 Feb 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '15 Feb 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '19 Feb 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '22 Feb 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '26 Feb 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '01 Mar 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '05 Mar 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '08 Mar 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '12 Mar 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '15 Mar 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '19 Mar 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '22 Mar 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '26 Mar 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '29 Mar 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '02 Apr 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '05 Apr 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '09 Apr 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '12 Apr 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '16 Apr 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '19 Apr 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '23 Apr 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '26 Apr 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '30 Apr 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '03 May 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '07 May 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '10 May 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '14 May 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '17 May 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '21 May 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '24 May 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '28 May 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '31 May 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '04 Jun 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '07 Jun 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '11 Jun 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '14 Jun 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '18 Jun 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '21 Jun 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '25 Jun 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '28 Jun 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '02 Jul 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '05 Jul 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '09 Jul 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '12 Jul 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '16 Jul 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '19 Jul 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '23 Jul 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '26 Jul 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '30 Jul 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '02 Aug 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '06 Aug 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '09 Aug 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '13 Aug 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '16 Aug 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '20 Aug 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '23 Aug 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '27 Aug 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '30 Aug 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '03 Sep 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '06 Sep 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '10 Sep 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '13 Sep 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '17 Sep 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '20 Sep 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '24 Sep 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '27 Sep 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '01 Oct 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '04 Oct 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '08 Oct 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '11 Oct 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '15 Oct 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '18 Oct 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:29:09
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '22 Oct 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:29:09

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-02-27T18:41:24-05:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1230a25d-8ee3-44f5-89c4-bf89be5b9470'	System	27 Feb 2021 23:41:37
User entered 'No (N)'	System	27 Feb 2021 23:41:37

US3402382
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary (1)
Generated On: 09 Jun 2021 17:29:09
Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2021-02-27T18:41:33-05:00', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1230a25d-8ee3-44f5-89c4-bf89be5b9470'	System	27 Feb 2021 23:41:37
User entered '27 Feb 2021 23:41:33'	System	27 Feb 2021 23:41:37

US3402382
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:30:13
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	09 Nov 2020 19:27:55

US3402382
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:30:13
User entered '09 Nov 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 13:33:31
User entered '9 Nov 2020'	Tammy Kohn (b) (4) (b) (4)	09 Nov 2020 19:27:55

US3402382
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:30:13
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4) (b) (4)	09 Nov 2020 19:27:55

US3402382
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:30:13
User entered empty.	Tammy Kohn (b) (4) (b) (4)	09 Nov 2020 19:27:55

FDA-CBER-2022-1614-1769561

US3402382
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:30:13
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	09 Nov 2020 19:27:58

FDA-CBER-2022-1614-1769562

US3402382
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:19:06
User entered '1'	System	09 Nov 2020 19:27:58

US3402382
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 20:50:26

US3402382
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '11 Dec 2020'	(b) (4), (b) (6)	14 Dec 2020 20:50:26

US3402382
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Dec 2020 20:50:26

US3402382
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:50:26

US3402382
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 20:50:32

FDA-CBER-2022-1614-1769568

US3402382
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User entered '1'	System	14 Dec 2020 20:50:32

US3402382
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 17:58:58

US3402382
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '11 Jan 2021'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 17:58:58

US3402382
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 17:58:58

FDA-CBER-2022-1614-1769572

US3402382
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Feb 2021 17:58:58

US3402382
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 17:59:03

FDA-CBER-2022-1614-1769574

US3402382
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User entered '1'	System	19 Feb 2021 17:59:03

FDA-CBER-2022-1614-1769575

US3402382
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 17:59:31

US3402382
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '8 Feb 2021'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 17:59:31

US3402382
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 17:59:31

US3402382
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Feb 2021 17:59:31

FDA-CBER-2022-1614-1769579

US3402382
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 17:59:35

US3402382
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User entered '1'	System	19 Feb 2021 17:59:35

US3402382
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:30:04

US3402382
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '18 Mar 2021'	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:30:04

US3402382
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:30:04

US3402382
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User entered 'VISIT4'	System	18 Mar 2021 15:30:04

FDA-CBER-2022-1614-1769585

US3402382
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 16:32:13

US3402382
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 16:32:13

FDA-CBER-2022-1614-1769587

US3402382
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 16:32:13

FDA-CBER-2022-1614-1769588

US3402382
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User entered empty.	System	31 Mar 2021 16:32:13

US3402382
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 16:32:13

US3402382
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 16:32:13

US3402382
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 16:32:13

US3402382
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 16:32:13

US3402382
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User entered empty.	System	31 Mar 2021 16:32:13

FDA-CBER-2022-1614-1769594

US3402382
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 16:32:13

US3402382
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User entered empty.	System	31 Mar 2021 16:32:13

FDA-CBER-2022-1614-1769596

US3402382
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 16:32:13

FDA-CBER-2022-1614-1769597

US3402382
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User entered empty.	System	31 Mar 2021 16:32:13

FDA-CBER-2022-1614-1769598

US3402382
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 16:32:13

FDA-CBER-2022-1614-1769599

US3402382
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User entered empty.	System	31 Mar 2021 16:32:13

FDA-CBER-2022-1614-1769600

US3402382
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51

FDA-CBER-2022-1614-1769601

US3402382
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51

FDA-CBER-2022-1614-1769602

US3402382
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:29:09
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:30:10

US3402382
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:29:09
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:30:10

FDA-CBER-2022-1614-1769604

US3402382
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
Comment added 'OL-3 KIT USED P ER PROTOCOL DUE TO BOTH VISITS BEING DONE AT SAME TIME.'.	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:31:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:30:51

US3402382
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '18 Mar 2021'	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:30:51

FDA-CBER-2022-1614-1769606

US3402382
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '11:14'	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:30:51

FDA-CBER-2022-1614-1769607

US3402382
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User entered '18 Mar 2021 11:14'	System	18 Mar 2021 15:30:51

FDA-CBER-2022-1614-1769608

US3402382
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:30:56

US3402382
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:10:51
User entered '1'	System	18 Mar 2021 15:30:56

FDA-CBER-2022-1614-1769610

US3402382
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	09 Apr 2021 13:08:59

US3402382
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '9 Apr 2021'	Traci Hull (b) (4) (b) (4)	09 Apr 2021 13:08:59

US3402382
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	09 Apr 2021 13:08:59

US3402382
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	09 Apr 2021 13:08:59

US3402382
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	09 Apr 2021 13:09:03

US3402382
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 13:09:03

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 17:29:09
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:33
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 28-Aug-2020 (Accession No: 1F636613352) is reported as an Illness Visit sample in PPD Central Labs however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.' (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 09:04:39
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:31
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 28-Aug-2020 (Accession No: 1F636613352) is reported as an Illness Visit sample in PPD Central Labs however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.' answered with 'DEF FORM SENT TO PPD AS OF 29MAR2021 TO CORRECT THE DATE TO THE 6TH OF AUGUST' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	29 Mar 2021 17:09:58
User entered '26 Aug 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	25 Mar 2021 19:21:45
User entered '28 Aug 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	25 Mar 2021 19:20:01
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 28-Aug-2020 (Accession No: 1F636613352) is reported as an Illness Visit sample in PPD Central Labs however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 10:55:17

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 17:29:09
Date of Contact

Audit	User	Time (GMT)
User closed query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (26Aug 2020). Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 14:08:37
Query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (26Aug 2020). Please review and reconcile.' answered with 'DATA IS CORRECT AS IS' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 14:40:14
User entered '26 Aug 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 14:40:05
User entered '25 Aug 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 14:39:12
User opened query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (26Aug 2020). Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 22:36:44
User closed query 'Per CDM: It appears subject reported symptoms; however, COVID Diagnostic Test form is not completed. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 15:41:16
Query 'Per CDM: It appears subject reported symptoms; however, COVID Diagnostic Test form is not completed. Please reconcile.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 13:30:07
User entered '26 Aug 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 13:30:01
User opened query 'Per CDM: It appears subject reported symptoms; however, COVID Diagnostic Test form is not completed. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 08:48:55
User entered '25 Aug 2020'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 12:40:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 17:29:09
Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:33
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:14:31
User entered '07:00'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 12:40:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 17:29:09
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:33
User entered '26 Aug 2020 07:00'	System	25 Mar 2021 19:21:45
User entered '28 Aug 2020 07:00'	System	25 Mar 2021 19:20:01
User entered '26 Aug 2020 07:00'	System	14 Jan 2021 14:40:05
User entered '25 Aug 2020 07:00'	System	14 Jan 2021 14:39:12
User entered '26 Aug 2020 07:00'	System	05 Oct 2020 13:30:01
User entered '25 Aug 2020 07:00'	System	04 Sep 2020 12:40:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 17:29:09
Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:14:31
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Traci Hull (b) (4)	04 Sep 2020 12:40:11

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US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 17:29:09
Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:33
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:14:31
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 12:40:11

FDA-CBER-2022-1614-1769622

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 14:39:51
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '26 Aug 2020'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '100'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

FDA-CBER-2022-1614-1769626

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User entered '%'	System	04 Sep 2020 13:55:01

FDA-CBER-2022-1614-1769627

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '99.5' F	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

FDA-CBER-2022-1614-1769629

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

FDA-CBER-2022-1614-1769631

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

FDA-CBER-2022-1614-1769634

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

FDA-CBER-2022-1614-1769640

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

FDA-CBER-2022-1614-1769641

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

FDA-CBER-2022-1614-1769642

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:29:09
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53
User entered 'Day 2 (Day 2)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '27 Aug 2020'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

FDA-CBER-2022-1614-1769646

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

FDA-CBER-2022-1614-1769647

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '100'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User entered '%'	System	04 Sep 2020 13:56:03

FDA-CBER-2022-1614-1769649

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '98.2' F	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

FDA-CBER-2022-1614-1769650

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

FDA-CBER-2022-1614-1769651

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

FDA-CBER-2022-1614-1769652

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

FDA-CBER-2022-1614-1769655

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

FDA-CBER-2022-1614-1769656

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

FDA-CBER-2022-1614-1769663

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

FDA-CBER-2022-1614-1769664

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:29:09
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53
User entered 'Day 3 (Day 3)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '28 Aug 2020'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

FDA-CBER-2022-1614-1769668

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '99'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

FDA-CBER-2022-1614-1769670

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User entered '%'	System	04 Sep 2020 13:57:00

FDA-CBER-2022-1614-1769671

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '96.8' F	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

FDA-CBER-2022-1614-1769672

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

FDA-CBER-2022-1614-1769673

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

FDA-CBER-2022-1614-1769674

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

FDA-CBER-2022-1614-1769677

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

FDA-CBER-2022-1614-1769678

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

FDA-CBER-2022-1614-1769680

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

FDA-CBER-2022-1614-1769685

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

FDA-CBER-2022-1614-1769686

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:29:09
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

FDA-CBER-2022-1614-1769688

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53
User entered 'Day 4 (Day 4)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '29 Aug 2020'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '1' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	13 Jan 2021 21:54:00
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

FDA-CBER-2022-1614-1769691

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
User closed query 'Per CDM re-query: Per previous query, please confirm if any assessments were carried out. If not, 'Assessment Not Done' should be checked and all other responses deleted. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 09:19:23
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	19 Jan 2021 21:55:34
Query 'Per CDM re-query: Per previous query, please confirm if any assessments were carried out. If not, 'Assessment Not Done' should be checked and all other responses deleted. Please review and update as appropriate. ' answered with 'DATA UPDATED ' (Site from DM).	Tammy Kohn (b) (4)	19 Jan 2021 21:55:27
User opened query 'Per CDM re-query: Per previous query, please confirm if any assessments were carried out. If not, 'Assessment Not Done' should be checked and all other responses deleted. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:40:31
Query 'Per CDM re-query: Per previous query, please confirm if any assessments were carried out. If not, 'Assessment Not Done' should be unchecked and all other responses deleted. Please review and update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:40:13
User opened query 'Per CDM re-query: Per previous query, please confirm if any assessments were carried out. If not, 'Assessment Not Done' should be unchecked and all other responses deleted. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:14:28
User closed query 'Per CDM re-query: 'Assessment Not Done' is checked however a response is recorded for 'Cough'. If any assessments were done, box should be unchecked and other values/symptoms entered as Not Done. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:14:28

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Query 'Per CDM re-query: 'Assessment Not Done' is checked however a response is recorded for 'Cough'. If any assessments were done, box should be unchecked and other values/symptoms entered as Not Done. Please review and update as appropriate.' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 12:34:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 12:34:13
User opened query 'Per CDM re-query: 'Assessment Not Done' is checked however a response is recorded for 'Cough'. If any assessments were done, box should be unchecked and other values/symptoms entered as Not Done. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 09:32:23
User closed query 'Per CDM: It appears that O2 saturation and temperature were not provided for days 4 - 7. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 09:32:23
Query 'Per CDM: It appears that O2 saturation and temperature were not provided for days 4 - 7. If not collected, please consider recording as Not Done.' answered with 'NOT DONE' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	13 Jan 2021 21:54:11
User opened query 'Per CDM: It appears that O2 saturation and temperature were not provided for days 4 - 7. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 22:39:30
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

FDA-CBER-2022-1614-1769693

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User entered empty.	System	19 Jan 2021 21:55:34
User entered '%'	System	18 Jan 2021 12:34:13
User entered empty.	System	04 Sep 2020 13:58:10

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User closed query 'Per CDM: As 'Assessment Not Done' is checked, therefore 'Not Done' is not required for these fields. Please delete.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 15:12:22
Query 'Per CDM: As 'Assessment Not Done' is checked, therefore 'Not Done' is not required for these fields. Please delete.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:20:05
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:19:57
User opened query 'Per CDM: As 'Assessment Not Done' is checked, therefore 'Not Done' is not required for these fields. Please delete.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 09:19:19
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:19:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Jan 2021 21:55:15
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:19:49
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:19:49
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:19:49
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:19:49
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

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US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:19:49
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:19:49
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:19:49
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:19:49
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:19:49
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:19:49
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:19:49
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:19:49
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:19:49
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:29:09
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:19:49
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

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US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53
User entered 'Day 5 (Day 5)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '30 Aug 2020'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

FDA-CBER-2022-1614-1769713

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User entered empty.	System	04 Sep 2020 13:58:57

FDA-CBER-2022-1614-1769716

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

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US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

FDA-CBER-2022-1614-1769731

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:29:09
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53
User entered 'Day 6 (Day 6)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

FDA-CBER-2022-1614-1769734

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '31 Aug 2020'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

FDA-CBER-2022-1614-1769735

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User entered empty.	System	04 Sep 2020 13:59:34

FDA-CBER-2022-1614-1769738

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

FDA-CBER-2022-1614-1769741

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

FDA-CBER-2022-1614-1769745

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

FDA-CBER-2022-1614-1769751

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:29:09
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

FDA-CBER-2022-1614-1769755

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53
User entered 'Day 7 (Day 7)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

FDA-CBER-2022-1614-1769756

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '01 Sep 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 13:57:16
User entered '1 Sep 2020'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User entered empty.	System	04 Sep 2020 14:00:11

FDA-CBER-2022-1614-1769760

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:29:09
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53
User entered 'Day 8 (Day 8)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '02 Sep 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 13:57:16
User entered '2 Sep 2020'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '100'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User entered '%'	System	04 Sep 2020 14:01:04

FDA-CBER-2022-1614-1769782

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '97.8' F	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

FDA-CBER-2022-1614-1769784

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

FDA-CBER-2022-1614-1769798

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:29:09
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53
User entered 'Day 9 (Day 9)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '03 Sep 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 13:57:16
User entered '3 Sep 2020'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '96'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

FDA-CBER-2022-1614-1769803

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User entered '%'	System	04 Sep 2020 14:01:46

FDA-CBER-2022-1614-1769804

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '36.1' C	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:29:09
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53
User entered 'Day 10 (Day 10)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '04 Sep 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 13:57:16
User entered '4 Sep 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

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US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '99'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

FDA-CBER-2022-1614-1769825

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User entered '%'	System	10 Sep 2020 13:10:04

FDA-CBER-2022-1614-1769826

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '96.4' F	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

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US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

FDA-CBER-2022-1614-1769841

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:29:09
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53
User entered 'Day 11 (Day 11)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '05 Sep 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 13:58:06
User entered '5 Sep 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

FDA-CBER-2022-1614-1769846

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '99'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

FDA-CBER-2022-1614-1769847

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User entered '%'	System	10 Sep 2020 13:11:01

FDA-CBER-2022-1614-1769848

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '96.0' F	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

FDA-CBER-2022-1614-1769855

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

FDA-CBER-2022-1614-1769857

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

FDA-CBER-2022-1614-1769862

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

FDA-CBER-2022-1614-1769863

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:29:09
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53
User entered 'Day 12 (Day 12)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

FDA-CBER-2022-1614-1769866

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '06 Sep 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 13:58:06
User entered '6 Sep 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '99'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User entered '%'	System	10 Sep 2020 13:13:23

FDA-CBER-2022-1614-1769870

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '96.9' F	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

FDA-CBER-2022-1614-1769871

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

FDA-CBER-2022-1614-1769872

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

FDA-CBER-2022-1614-1769873

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

FDA-CBER-2022-1614-1769879

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

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US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

FDA-CBER-2022-1614-1769884

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:29:09
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53
User entered 'Day 13 (Day 13)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '07 Sep 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 13:58:06
User entered '7 Sep 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

FDA-CBER-2022-1614-1769890

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '100'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

FDA-CBER-2022-1614-1769891

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User entered '%'	System	10 Sep 2020 13:14:11

FDA-CBER-2022-1614-1769892

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '36.4' C	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

FDA-CBER-2022-1614-1769894

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

FDA-CBER-2022-1614-1769897

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

FDA-CBER-2022-1614-1769898

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

FDA-CBER-2022-1614-1769899

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

FDA-CBER-2022-1614-1769901

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

FDA-CBER-2022-1614-1769905

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

FDA-CBER-2022-1614-1769907

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 17:29:09
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53
User entered 'Day 14 (Day 14)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '08 Sep 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 13:58:06
User entered '8 Sep 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

FDA-CBER-2022-1614-1769911

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '99'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

FDA-CBER-2022-1614-1769913

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User entered '%'	System	10 Sep 2020 13:15:00

FDA-CBER-2022-1614-1769914

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '96.4' F	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

FDA-CBER-2022-1614-1769915

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

FDA-CBER-2022-1614-1769916

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

FDA-CBER-2022-1614-1769917

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

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US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

FDA-CBER-2022-1614-1769923

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

FDA-CBER-2022-1614-1769928

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

FDA-CBER-2022-1614-1769929

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 17:29:09
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53
User entered 'Day 15 (Day 15)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '09 Sep 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 13:58:06
User entered '9 Sep 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

FDA-CBER-2022-1614-1769934

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '100'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User entered '%'	System	10 Sep 2020 20:36:51

FDA-CBER-2022-1614-1769936

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '96.9' F	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

FDA-CBER-2022-1614-1769938

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

FDA-CBER-2022-1614-1769939

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

FDA-CBER-2022-1614-1769941

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

FDA-CBER-2022-1614-1769942

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

FDA-CBER-2022-1614-1769943

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

FDA-CBER-2022-1614-1769944

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

FDA-CBER-2022-1614-1769945

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

FDA-CBER-2022-1614-1769946

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

FDA-CBER-2022-1614-1769947

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

FDA-CBER-2022-1614-1769948

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

FDA-CBER-2022-1614-1769950

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

FDA-CBER-2022-1614-1769951

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

FDA-CBER-2022-1614-1769952

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 17:29:09
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

FDA-CBER-2022-1614-1769953

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53
User entered 'Day 16 (Day 16)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

FDA-CBER-2022-1614-1769954

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '10 Sep 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

FDA-CBER-2022-1614-1769955

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

FDA-CBER-2022-1614-1769956

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '95'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User entered '%'	System	10 Sep 2020 20:37:27

FDA-CBER-2022-1614-1769958

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '97.9' F	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

FDA-CBER-2022-1614-1769960

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

FDA-CBER-2022-1614-1769961

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

FDA-CBER-2022-1614-1769962

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

FDA-CBER-2022-1614-1769963

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

FDA-CBER-2022-1614-1769964

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

FDA-CBER-2022-1614-1769965

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

FDA-CBER-2022-1614-1769966

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

FDA-CBER-2022-1614-1769967

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

FDA-CBER-2022-1614-1769972

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

FDA-CBER-2022-1614-1769973

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

FDA-CBER-2022-1614-1769974

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 17:29:09
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

FDA-CBER-2022-1614-1769975

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Day 18 (Day 18)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53
User entered 'Day 17 (Day 17)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '11 Sep 2020'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '0'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

FDA-CBER-2022-1614-1769978

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '99'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

FDA-CBER-2022-1614-1769979

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User entered '%'	System	14 Sep 2020 17:15:22

FDA-CBER-2022-1614-1769980

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '97.6' F	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

FDA-CBER-2022-1614-1769982

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

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US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 17:29:09
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Day 19 (Day 19)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53
User entered 'Day 18 (Day 18)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '12 Oct 2020'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '0'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '98'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User entered '%'	System	21 Oct 2020 11:50:58

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US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '97.4' F	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

FDA-CBER-2022-1614-1770004

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

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US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (18)
Generated On: 09 Jun 2021 17:29:09
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Day 20 (Day 20)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53
User entered 'Day 19 (Day 19)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '13 Oct 2020'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '0'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '99'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User entered '%'	System	21 Oct 2020 11:51:39

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US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '97.7' F	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

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US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (19)
Generated On: 09 Jun 2021 17:29:09
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Day 1 (Day 1)'	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '25 Aug 2020'	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '1'	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User entered empty.	System	20 Apr 2021 17:37:53

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US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

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US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Symptom Log (20)
Generated On: 09 Jun 2021 17:29:09
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 17:37:53

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 17:29:09
Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:39
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 28 AUG 2020 is reported under UNSCHEDULED Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:59:04
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 28 AUG 2020 is reported under UNSCHEDULED Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Sample was collected 28Aug2020 ' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 14:04:00
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 28 AUG 2020 is reported under UNSCHEDULED Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:20:06
User entered '26 Aug 2020'	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 12:13:44

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 17:29:09
Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:18:39
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 12:13:44

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 17:29:09
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:18:39
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 12:13:44

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 17:29:09
Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:18:39
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated “26-AUG-2020” is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as “28-AUG-2020” for Illness visit Day 1. Kindly review the collection date and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 08:01:21
Query 'Per GCL Lab Reconciliation: Swab: Sample dated “26-AUG-2020” is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as “28-AUG-2020” for Illness visit Day 1. Kindly review the collection date and update as appropriate, else clarify.' answered with 'ppd is incorrect. edc is correct' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	17 Dec 2020 20:39:10
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated “26-AUG-2020” is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as “28-AUG-2020” for Illness visit Day 1. Kindly review the collection date and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 05:33:54
User entered '26 Aug 2020'	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 12:13:44

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 17:29:09
Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:18:39
User entered 'Nasal Swab (Nasal Swab)'	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 12:13:44

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US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 17:29:09
Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:18:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 12:13:44

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 17:29:09
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)	03 May 2021 00:22:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:39
User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	05 Oct 2020 12:14:17
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	05 Oct 2020 12:13:55
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 12:13:55
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 12:13:44

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 17:29:09
Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:39
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Oct 2020 12:13:55
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Oct 2020 12:13:44
User entered empty.	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 12:13:44

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 17:29:09
CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:18:39
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	05 Oct 2020 12:14:17
User entered 'No (N)'	Tammy Kohn (b) (4)	05 Oct 2020 12:13:44

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 17:29:09
COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:43
User entered '0'	System	05 Oct 2020 12:13:44

FDA-CBER-2022-1614-1770073

US3402382
Folder: Covid-19 Assessment 26 Aug 2020
Form: Generate Next COVID-19 Assessment
Generated On: 09 Jun 2021 17:29:09
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:48
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:18:46
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 12:14:29

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 09 Jun 2021 17:29:09
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

FDA-CBER-2022-1614-1770075

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 09 Jun 2021 17:29:09
Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 09 Jun 2021 17:29:09
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 28AUG2020, 01SEP2020 and 08SEP2020 for Day 3, Day 7 and Day 14 is recorded in EDC central lab, however same is reported with 31AUG2020, 03SEP2020 and 09SEP2020 for Day 3, Day 7 and Day 14 in PPD Central lab. Please reconcile and update if applicable, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 06:51:49
Query 'Per GCL Lab Recon: Saliva: Sample dated 28AUG2020, 01SEP2020 and 08SEP2020 for Day 3, Day 7 and Day 14 is recorded in EDC central lab, however same is reported with 31AUG2020, 03SEP2020 and 09SEP2020 for Day 3, Day 7 and Day 14 in PPD Central lab. Please reconcile and update if applicable, else clarify. Thank you.' answered with 'Dates in EDC are correct' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 12:42:58
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 28AUG2020, 01SEP2020 and 08SEP2020 for Day 3, Day 7 and Day 14 is recorded in EDC central lab, however same is reported with 31AUG2020, 03SEP2020 and 09SEP2020 for Day 3, Day 7 and Day 14 in PPD Central lab. Please reconcile and update if applicable, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:52:32
User entered '28 Aug 2020'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 09 Jun 2021 17:29:09
Visit

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 31AUG2020 and 09SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:42:05
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 31AUG2020 and 09SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'NO SAMPLE DONE AS PATIENT WAS IN THE HOSPITAL' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	19 Nov 2020 13:41:47
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 31AUG2020 and 09SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 05:10:49
User accepted default value 'Day 5 (Day 5)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 09 Jun 2021 17:29:09
Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 09 Jun 2021 17:29:09
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31AUG2020 and 09SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 06:59:49
User entered empty; reason for change New Information	Jennifer Molstead (b) (4) (b) (4)	24 Nov 2020 17:52:16
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31AUG2020 and 09SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' answered with 'SUBJECT DID NOT COLLECT THIS SAMPLE' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	24 Nov 2020 17:51:59
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31AUG2020 and 09SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:42:19
User entered '30 Aug 2020'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

FDA-CBER-2022-1614-1770080

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 09 Jun 2021 17:29:09
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

FDA-CBER-2022-1614-1770081

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 09 Jun 2021 17:29:09
Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 09 Jun 2021 17:29:09
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 10:13:16
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	15 Feb 2021 21:27:45
User entered '01 Sep 2020' reason for change: New Information	Tammy Kohn (b) (4) (b) (4)	15 Feb 2021 21:27:39
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 04:23:15
User closed query 'Per CDM: Was Saliva Collected? is noted as NO however Date of Collection is recorded. Please review and update accordingly. else clarify.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:09:17
Query 'Per CDM: Was Saliva Collected? is noted as NO however Date of Collection is recorded. Please review and update accordingly. else clarify.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:24:45
User entered empty; reason for change New Information	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:24:36
User opened query 'Per CDM: Was Saliva Collected? is noted as NO however Date of Collection is recorded. Please review and update accordingly. else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 09:28:32

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 09 Jun 2021 17:29:09
Date of Collection

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:01:52
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	11 Jan 2021 13:54:23
User entered '01 Sep 2020' reason for change: New Information	Tammy Kohn (b) (4) (b) (4)	11 Jan 2021 13:54:17
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Jan 2021 13:54:03
User entered empty; reason for change New Information	Tammy Kohn (b) (4) (b) (4)	11 Jan 2021 13:54:03
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Jan 2021 13:53:54
User entered 'ND ND' (non-conformant).	Tammy Kohn (b) (4) (b) (4)	11 Jan 2021 13:53:54
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 04:12:42
User entered empty; reason for change New Information	Jennifer Molstead (b) (4) (b) (4)	24 Nov 2020 17:52:37
User entered '01 Sep 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 13:58:54
User entered '1 Sep 2020'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 09 Jun 2021 17:29:09
Visit

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Requery 1:please provide accession number for reference for Lab .thnaks' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 08:26:19
Query 'Per GCL Lab Reconciliation: Saliva: Requery 1:please provide accession number for reference for Lab .thnaks' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:25:06
User opened query 'Per GCL Lab Reconciliation: Saliva: Requery 1:please provide accession number for reference for Lab .thnaks' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 06:06:02
User closed query 'Per GCL Lab Reconciliation: Saliva: Requery 1:please provide accession number for reference.thnaks' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 06:06:02
Query 'Per GCL Lab Reconciliation: Saliva: Requery 1:please provide accession number for reference.thnaks' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	19 Jan 2021 22:17:08
User opened query 'Per GCL Lab Reconciliation: Saliva: Requery 1:please provide accession number for reference.thnaks' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:02:00
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03SEP2020 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:02:00
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03SEP2020 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'OUR LAB TECH HAS SENT THE UPDATED INFORMATION TO PPD TO HAVE UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	06 Jan 2021 20:42:57

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US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 09 Jun 2021 17:29:09
Visit

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03SEP2020 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 05:26:08
User accepted default value 'Day 9 (Day 9)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 09 Jun 2021 17:29:09
Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Jan 2021 22:17:03
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 09 Jun 2021 17:29:09
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty; reason for change New Information	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:24:59
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03SEP2020 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 06:37:59
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03SEP2020 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'PAPERWORK HAS BEEN SET TO PPD CENTRAL LAB TO CORRECT THE INFORMATION.' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	04 Dec 2020 16:26:12
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03SEP2020 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 06:32:11
User entered '03 Sep 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 13:58:54
User entered '3 Sep 2020'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 09 Jun 2021 17:29:09
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

FDA-CBER-2022-1614-1770089

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 09 Jun 2021 17:29:09
Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 09 Jun 2021 17:29:09
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '08 Sep 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 13:58:54
User entered '8 Sep 2020'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 09 Jun 2021 17:29:09
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

FDA-CBER-2022-1614-1770092

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 09 Jun 2021 17:29:09
Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 14:23:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 14:23:36
User entered 'No (N)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:23:36
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 11:44:15
User entered empty.	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 09 Jun 2021 17:29:09
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty; reason for change New Information	Jennifer Molstead (b) (4) (b) (4)	24 Nov 2020 17:53:09
User entered '27 Oct 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:23:36
User entered empty.	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 09 Jun 2021 17:29:09
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

FDA-CBER-2022-1614-1770095

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 09 Jun 2021 17:29:09
Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 14:23:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 14:23:36
User entered 'No (N)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:23:36
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 11:44:15
User entered empty.	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 09 Jun 2021 17:29:09
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty; reason for change New Information	Jennifer Molstead (b) (4) (b) (4)	24 Nov 2020 17:53:09
User entered '27 Oct 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:23:36
User entered empty.	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:59:44
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 28 AUG 2020 is reported under UNSCHEDULED Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:19:55
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 28 AUG 2020 is reported under UNSCHEDULED Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:19:30
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:17:20

US3402382
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:59:44
User entered '26 Aug 2020'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:17:20

US3402382
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:59:44
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:17:20

US3402382
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User entered 'SICKD1'	System	26 Aug 2020 19:17:20

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US3402382
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:01:18
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:12

US3402382
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:01:18
User entered '26 Aug 2020'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:12

US3402382
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:01:18
User entered '12:51'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:12

US3402382
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User entered '26 Aug 2020 12:51'	System	26 Aug 2020 19:19:12

US3402382
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:01:18
User entered '187.9' cm	Traci Hull (b) (4)	26 Aug 2020 19:19:12
DataPoint set to visible.	System	26 Aug 2020 19:17:20

US3402382
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:01:18
User entered '127.9' kg	Traci Hull (b) (4)	26 Aug 2020 19:19:12
DataPoint set to visible.	System	26 Aug 2020 19:17:20

US3402382
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:01:18
User entered '99.5' F	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:12

US3402382
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:01:18
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:12

US3402382
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:01:18
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:12

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US3402382
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:01:18
User closed query 'Per CDM: Per previous query, please confirm if this value should be considered NCS or not.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 12:24:36
Query 'Per CDM: Per previous query, please confirm if this value should be considered NCS or not.' answered with 'This was considered clinically significant. Patient was advised to go to the Emergency Room. Patient declined' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	16 Sep 2020 17:07:56
User opened query 'Per CDM: Per previous query, please confirm if this value should be considered NCS or not.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 10:43:48
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 10:43:20
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CORRECT AS IS' (Site from System).	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 01:42:34
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	26 Aug 2020 19:19:12
User entered '137'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:12

US3402382
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User entered 'bpm'	System	26 Aug 2020 19:19:12

FDA-CBER-2022-1614-1770112

US3402382
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:01:18
User entered '16'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:12

US3402382
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User entered 'breaths/min'	System	26 Aug 2020 19:19:12

US3402382
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:01:18
User entered '120'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:12

US3402382
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User entered 'mmHg'	System	26 Aug 2020 19:19:12

FDA-CBER-2022-1614-1770116

US3402382
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:01:18
User entered '86'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:12

US3402382
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User entered 'mmHg'	System	26 Aug 2020 19:19:12

FDA-CBER-2022-1614-1770118

US3402382
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34

FDA-CBER-2022-1614-1770119

US3402382
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34

FDA-CBER-2022-1614-1770120

US3402382
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:29:09
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:01:28
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:33

US3402382
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:29:09
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:01:28
User entered '26 Aug 2020'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:33

US3402382
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 09 Jun 2021 17:29:09
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:10:23
User closed query 'Per GCL Lab Recon: GCL has Saliva Day 3, Day 7, and Day 14 with dates of 31AUG2020, 03SEP2020, and 09SEP2020 respectively; however there is no Saliva Log completed. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 09:50:12
Query 'Per GCL Lab Recon: GCL has Saliva Day 3, Day 7, and Day 14 with dates of 31AUG2020, 03SEP2020, and 09SEP2020 respectively; however there is no Saliva Log completed. Please reconcile or clarify' answered with 'Log has been updated' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 14:02:23
User opened query 'Per GCL Lab Recon: GCL has Saliva Day 3, Day 7, and Day 14 with dates of 31AUG2020, 03SEP2020, and 09SEP2020 respectively; however there is no Saliva Log completed. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 20:56:47
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:20:38

US3402382
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 09 Jun 2021 17:29:09
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:34
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
User closed query 'Per source, sample was collected on 26-AUG-2020. Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 19:10:45
Query 'Per source, sample was collected on 26-AUG-2020. Please review and update entries.' answered with 'Sample was actually recollected due to a processing issue. This date is correct' (Site from CRA).	Jennifer Molstead (b) (4)	20 Apr 2021 17:43:19
User opened query 'Per source, sample was collected on 26-AUG-2020. Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 17:13:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:10:23
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 28 AUG 2020 is reported under illness visit Day 1 in EDC, however the same is reported in the UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 12:01:42
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 28 AUG 2020 is reported under illness visit Day 1 in EDC, however the same is reported in the UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' answered with 'DATA HAS BEEN SET TO PPD TO UPDATE THE INFORMATION TO ILLNESS VISIT.' (Site from DM).	Tammy Kohn (b) (4)	11 Nov 2020 17:05:26

US3402382
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 09 Jun 2021 17:29:09
Date of Collection

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 28 AUG 2020 is reported under illness visit Day 1 in EDC, however the same is reported in the UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 05:54:30
User entered '28 Aug 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 14:03:22
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 26 AUG 2020 is reported under illness Visit in EDC, however the Sample dated 28 AUG 2020 is recorded under illness visit in PPD Central lab. Please confirm the correct Visit date and update if applicable. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:17:46
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 26 AUG 2020 is reported under illness Visit in EDC, however the Sample dated 28 AUG 2020 is recorded under illness visit in PPD Central lab. Please confirm the correct Visit date and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:14:08
User entered '26 Aug 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	06 Oct 2020 17:09:10
User entered '28 Aug 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 17:59:45
User entered '26 Aug 2020'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:20:38

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:41:33

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '23 Jan 2021'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:41:33

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:41:33

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'UNBLND_DECIDE'	System	23 Jan 2021 18:41:33

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:29:09
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '06 Jan 2021'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:42:06

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:29:09
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '0'	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 14:02:17
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:49:46

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:29:09
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:42:06

US3402382

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:29:09

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field' (Site from DM).	(b) (4), (b) (6)	10 Apr 2021 06:08:56
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 14:02:30
User entered 'Amendment 6 or later (Amendment 6 or later)'	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 14:02:17
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:04:52
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:49:46

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:29:09
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '23 Jan 2021'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:42:06

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:29:09
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Placebo (Placebo)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:42:06

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:29:09
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Placebo (Placebo)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:42:06

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:29:09
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Placebo (Placebo)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:42:06

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:29:09
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:42:06

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:29:09
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered '1'	System	23 Jan 2021 18:42:06

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:29:09
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered '1'	System	23 Jan 2021 18:42:06

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:29:09
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

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US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:29:09
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:29:09
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered empty.	System	23 Jan 2021 18:44:40
DataPoint set to visible.	System	23 Jan 2021 18:42:06

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:29:09
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:29:09
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:29:09
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered empty.	System	23 Jan 2021 18:44:40
DataPoint set to visible.	System	23 Jan 2021 18:42:06

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '23 Jan 2021'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

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US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '11:30'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered '23 Jan 2021 11:30'	System	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '36.5' C	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '56'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'bpm'	System	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '14'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'breaths/min'	System	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '105'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'mmHg'	System	23 Jan 2021 18:44:40

FDA-CBER-2022-1614-1770160

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '65'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'mmHg'	System	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:29:09
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:29:09
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:29:09
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered empty.	System	23 Jan 2021 18:44:40
DataPoint set to visible.	System	23 Jan 2021 18:42:06

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '23 Jan 2021'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '12:29'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered '23 Jan 2021 12:29'	System	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '36.5' C	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

FDA-CBER-2022-1614-1770173

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '56'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'bpm'	System	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '16'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'breaths/min'	System	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '113'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'mmHg'	System	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '69'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'mmHg'	System	23 Jan 2021 18:44:40

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:29:09
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:47

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:29:09
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '23 Jan 2021'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:44:47

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:45:15

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:45:15

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
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)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:45:15

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'mRNA-1273'	System	23 Jan 2021 18:45:15
DataPoint set to visible.	System	23 Jan 2021 18:42:06

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '23 Jan 2021'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:45:15

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '11:50'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:45:15

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered '23 Jan 2021 11:50'	System	23 Jan 2021 18:45:15

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Left Arm (LEFT ARM)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:45:15

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'ONCE'	System	23 Jan 2021 18:45:15

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'INTRAMUSCULAR'	System	23 Jan 2021 18:45:15

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:42:26

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '23 Jan 2021'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:42:26

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '11:19'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:42:26

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered '23 Jan 2021 11:19'	System	23 Jan 2021 18:42:26

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 17:29:09
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:42:36

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 17:29:09
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '23 Jan 2021'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:42:36

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 17:29:09
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '11:20'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:42:36

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 17:29:09
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered '23 Jan 2021 11:20'	System	23 Jan 2021 18:42:36

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 18:42:41

US3402382
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered '1'	System	23 Jan 2021 18:42:41

US3402382
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 17:59:51

US3402382
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '1 Feb 2021'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 17:59:51

US3402382
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 17:59:51

US3402382
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Feb 2021 17:59:51

US3402382
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 17:59:56

US3402382
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered '1'	System	19 Feb 2021 17:59:56

US3402382
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered '1'	System	19 Feb 2021 17:59:56
DataPoint set to visible.	System	19 Feb 2021 17:59:56

US3402382
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:00:13

US3402382
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '19 Feb 2021'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:00:13

US3402382
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Home (Home)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:00:13

US3402382
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'OLD29'	System	19 Feb 2021 18:00:13

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US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '19 Feb 2021'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '11:46'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

FDA-CBER-2022-1614-1770218

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered '19 Feb 2021 11:46'	System	19 Feb 2021 18:01:41

FDA-CBER-2022-1614-1770219

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '36.2' C	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

FDA-CBER-2022-1614-1770220

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

FDA-CBER-2022-1614-1770221

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '58'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

FDA-CBER-2022-1614-1770223

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'bpm'	System	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '14'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'breaths/min'	System	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '128'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'mmHg'	System	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '86'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'mmHg'	System	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

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US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '19 Feb 2021'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '12:36'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered '19 Feb 2021 12:36'	System	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '36.9' C	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

FDA-CBER-2022-1614-1770236

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '78'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'bpm'	System	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '15'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'breaths/min'	System	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '120'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'mmHg'	System	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '82'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'mmHg'	System	19 Feb 2021 18:01:41

US3402382
Folder: OL-D29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:29:09
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:55

US3402382
Folder: OL-D29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:29:09
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '19 Feb 2021'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:01:55

US3402382
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:02:10

US3402382
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:02:10

US3402382
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
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)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:02:10

US3402382
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'mRNA-1273'	System	19 Feb 2021 18:02:10
DataPoint set to visible.	System	19 Feb 2021 17:59:56

US3402382
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '19 Feb 2021'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:02:10

US3402382
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '12:05'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:02:10

US3402382
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered '19 Feb 2021 12:05'	System	19 Feb 2021 18:02:10

US3402382
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Left Arm (LEFT ARM)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:02:10

US3402382
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'ONCE'	System	19 Feb 2021 18:02:10

US3402382
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:29:09
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'INTRAMUSCULAR'	System	19 Feb 2021 18:02:10

US3402382
Folder: OL-D29 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 18:02:14

US3402382
Folder: OL-D29 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered '1'	System	19 Feb 2021 18:02:14

FDA-CBER-2022-1614-1770260

US3402382
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Feb 2021 16:16:33

US3402382
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '26 Feb 2021'	Traci Hull (b) (4) (b) (4)	26 Feb 2021 16:16:33

US3402382
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	26 Feb 2021 16:16:33

US3402382
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:29:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Feb 2021 16:16:33

US3402382
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Feb 2021 16:16:23

US3402382
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:29:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered '1'	System	26 Feb 2021 16:16:23

FDA-CBER-2022-1614-1770266

US3402382
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:32:14

US3402382
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '18 Mar 2021'	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:32:14

US3402382
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:32:14

US3402382
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:29:09
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered 'OLD57'	System	18 Mar 2021 15:32:14

FDA-CBER-2022-1614-1770270

US3402382
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:32:26

US3402382
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:32:26

US3402382
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:32:26

US3402382
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered empty.	System	18 Mar 2021 15:32:26

US3402382
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:32:26

US3402382
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:32:26

US3402382
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:32:26

US3402382
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:32:26

US3402382
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered empty.	System	18 Mar 2021 15:32:26

US3402382
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:32:26

FDA-CBER-2022-1614-1770280

US3402382
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered empty.	System	18 Mar 2021 15:32:26

US3402382
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:32:26

FDA-CBER-2022-1614-1770282

US3402382
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered empty.	System	18 Mar 2021 15:32:26

FDA-CBER-2022-1614-1770283

US3402382
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:32:26

US3402382
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered empty.	System	18 Mar 2021 15:32:26

US3402382
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25

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US3402382
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:29:09
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25

FDA-CBER-2022-1614-1770287

US3402382
Folder: OL-D57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:29:09
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:32:30

US3402382
Folder: OL-D57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:29:09
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:32:30

US3402382
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:33:09

US3402382
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '18 Mar 2021'	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:33:09

FDA-CBER-2022-1614-1770291

US3402382
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
User entered '11:14'	Traci Hull (b) (4) (b) (4)	18 Mar 2021 15:33:09

US3402382
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:29:09
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:25
User entered '18 Mar 2021 11:14'	System	18 Mar 2021 15:33:09

US3402382
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 17:29:09
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:52
User closed query 'Per CDM re-query: Response indicates 'FATIGUE WITHIN 7 DAYS OF INJECTION'. However there is record of Fatigue beyond day 7 (Day 8: 23 AUG). Please review and confirm if the subject recorded FATIGUE for Day 8 in error else add the AE (Day 3-8) as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 14:50:04
Query 'Per CDM re-query: Response indicates 'FATIGUE WITHIN 7 DAYS OF INJECTION'. However there is record of Fatigue beyond day 7 (Day 8: 23 AUG). Please review and confirm if the subject recorded FATIGUE for Day 8 in error else add the AE (Day 3-8) as appropriate. ' answered with 'reactivated ae' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:42:19
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 3; end date: Day 8). 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)	08 Apr 2021 11:08:16
User opened query 'Per CDM re-query: Response indicates 'FATIGUE WITHIN 7 DAYS OF INJECTION'. However there is record of Fatigue beyond day 7 (Day 8: 23 AUG). Please review and confirm if the subject recorded FATIGUE for Day 8 in error else add the AE (Day 3-8) as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:08:15
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 3; end date: Day 8). 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 'FATIGUE WITHIN 7 DAYS OF INJECTION' (Site from DM).	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:09:17

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US3402382
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 17:29:09
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 3; end date: Day 8). 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)	21 Mar 2021 11:24:15
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:58:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 10:27:17
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:38

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
AEID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:41
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 21:56:41
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:11:38
User entered 'USA-US059-2020-mRNA-1273-P301000002'	System	02 Sep 2020 13:11:09
User entered 'New'	(b) (4), (b) (6)	02 Sep 2020 13:11:09

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:25
User closed query 'Per AE log, Atrial Fibrillation was the AE. Please review and update eCRF or AE Log.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:47:19
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4)	07 Nov 2020 15:05:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Nov 2020 15:05:33
Data point term sent to Coder	System	07 Nov 2020 15:04:58
Query 'Per AE log, Atrial Fibrillation was the AE. Please review and update eCRF or AE Log.' answered with 'UPdated' (Site from CRA).	Jennifer Molstead (b) (4)	07 Nov 2020 15:04:32
DataPoint Un-verified.	Jennifer Molstead (b) (4)	07 Nov 2020 15:04:22
Coding entries removed.	Jennifer Molstead (b) (4)	07 Nov 2020 15:04:22
User entered 'ATRIAL Fibrillation' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 15:04:22
User opened query 'Per AE log, Atrial Fibrillation was the AE. Please review and update eCRF or AE Log.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 21:57:36
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User closed query 'PV Query: Please confirm if the fall met criteria for separate AE reporting.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:25:24
Query 'PV Query: Please confirm if the fall met criteria for separate AE reporting.' answered with 'It did not' (Site from Safety).	Jennifer Molstead (b) (4)	14 Sep 2020 01:30:53
User opened query 'PV Query: Please confirm if the fall met criteria for separate AE reporting.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:46:13
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial flutter, LLT: Atrial flutter - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 11:03:41

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Adverse event

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 11:03:41
Data point term sent to Coder	System	02 Sep 2020 11:02:51
User entered 'Atrial Flutter'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:55:43
User closed query 'PV Query: On 26 Aug 2020, the subject's pulse was 139 at convalescent visit. Was the subject diagnosed with COVID-19? If yes, please consider reporting COVID-19 as an additional AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 17:20:54
Query 'PV Query: On 26 Aug 2020, the subject's pulse was 139 at convalescent visit. Was the subject diagnosed with COVID-19? If yes, please consider reporting COVID-19 as an additional AE/SAE.' answered with 'NO COVID TEST CAME BACK NEGATIVE, SAE ALREADY LOGGED' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 18:50:43
User opened query 'PV Query: On 26 Aug 2020, the subject's pulse was 139 at convalescent visit. Was the subject diagnosed with COVID-19? If yes, please consider reporting COVID-19 as an additional AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 17:22:08
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	16 Sep 2020 23:59:08
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	14 Sep 2020 16:12:18
User entered '28 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	14 Sep 2020 01:33:58
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Sep 2020 01:33:58
User entered empty; reason for change Data Entry Error	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 01:33:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 11:02:13
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	02 Sep 2020 11:02:13
User entered 'UN:UN' (non-conformant).	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

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US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 01:33:58
User entered '28 Aug 2020 UN:UN' (non-conformant).	System	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '1 Sep 2020'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	14 Sep 2020 01:33:58
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Sep 2020 01:33:58
User entered empty; reason for change Data Entry Error	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 01:33:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 11:02:13
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	02 Sep 2020 11:02:13
User entered 'UN:UN' (non-conformant).	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 01:33:58
User entered '1 Sep 2020 UN:UN' (non-conformant).	System	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Severity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:55:43
User closed query 'PV Query: As the event required hospitalization, please consider changing intensity to grade 3. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:25:41
Query 'PV Query: As the event required hospitalization, please consider changing intensity to grade 3. If not, please clarify.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 01:34:15
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 01:33:58
User opened query 'PV Query: As the event required hospitalization, please consider changing intensity to grade 3. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:42:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '1'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '28 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '1 Sep 2020'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'None (NONE)'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
None

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
Signature has been broken.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
Query 'PV Query: Please add stop dates or tick ongoing for all concomitant medications.' canceled (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:28:19
User opened query 'PV Query: Please add stop dates or tick ongoing for all concomitant medications.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:41:48
User entered '1'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:33:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
User closed query 'Per DM CLR: Noted Other action taken = Concomitant Procedure. Please disregard query in Con procedure eCRF. Please note that Diagnostic procedures are not considered treatment. Please review and add therapeutic procedure as appropriate or update Treatment Required field.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 06:06:45
Query 'Per DM CLR: Noted Other action taken = Concomitant Procedure. Please disregard query in Con procedure eCRF. Please note that Diagnostic procedures are not considered treatment. Please review and add therapeutic procedure as appropriate or update Treatment Required field.' answered with 'REMOVED FLAG FOR CONCOMITANT PROCEDURE PER QUERY' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	08 Mar 2021 19:10:11
User entered '0' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	08 Mar 2021 19:09:44
User opened query 'Per DM CLR: Noted Other action taken = Concomitant Procedure. Please disregard query in Con procedure eCRF. Please note that Diagnostic procedures are not considered treatment. Please review and add therapeutic procedure as appropriate or update Treatment Required field.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 01:59:02
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 17:30:27
User entered '1' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 17:30:27
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

FDA-CBER-2022-1614-1770326

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Outcome

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:55:43
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	30 Oct 2020 14:46:41
User closed query 'PV Query: Thank you for reporting that SAE was resolved since subject's heart rate was back to normal Please consider updating the outcome in the EDC to recovered/resolved (currently reported as recovered/resolved with sequelae).' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:03:35
Query 'PV Query: Thank you for reporting that SAE was resolved since subject's heart rate was back to normal Please consider updating the outcome in the EDC to recovered/resolved (currently reported as recovered/resolved with sequelae).' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	29 Oct 2020 21:33:56
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	29 Oct 2020 21:33:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	29 Oct 2020 21:33:27
User opened query 'PV Query: Thank you for reporting that SAE was resolved since subject's heart rate was back to normal Please consider updating the outcome in the EDC to recovered/resolved (currently reported as recovered/resolved with sequelae).' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:21:31
User closed query 'PV Query: "pending cardiologist follow-up" can't be considered as sequelae. If the subject was in a-fib at the time of hospital discharge, please consider updating outcome to ongoing.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 17:21:04

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Outcome

Audit	User	Time (GMT)
Query 'PV Query: "pending cardiologist follow-up" can't be considered as sequelae. If the subject was in a-fib at the time of hospital discharge, please consider updating outcome to ongoing.' answered with 'SAE IS RESOLVED SINCE PATIENT'S HEART RATE IS BACK TO NORMAL. THE PATIENT WILL FOLLOW UP WITH A CARDIOLOGIST TO FIGURE OUT WHY THE EVEN IS HAPPENING' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 18:49:57
User opened query 'PV Query: "pending cardiologist follow-up" can't be considered as sequelae. If the subject was in a-fib at the time of hospital discharge, please consider updating outcome to ongoing.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 17:21:43
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	30 Oct 2020 14:46:41
User entered 'Subject will follow up with cardiologist on an outpatient basis.'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
User closed query 'Per DM CLR: Narrative indicates that the subject had CT of Head and Brain and a Chest Xray. However, there is no corresponding Concomitant Procedure record that match the information. Please update to record the correspoding procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 09:29:02
Query 'Per DM CLR: Narrative indicates that the subject had CT of Head and Brain and a Chest Xray. However, there is no corresponding Concomitant Procedure record that match the information. Please update to record the correspoding procedures as appropriate. Otherwise, clarify.' answered with 'CT AND CHEST XRAY ADDED TO CONCOMITANT PROCEDURE.' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	30 Nov 2020 21:07:35
User opened query 'Per DM CLR: Narrative indicates that the subject had CT of Head and Brain and a Chest Xray. However, there is no corresponding Concomitant Procedure record that match the information. Please update to record the correspoding procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 17:24:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:38
User closed query 'PV Query: Thank you for providing dates when COVID-19 test was done. However, the date was reported as Oct. Please confirm if the month was Oct or Aug since the event occurred in AUG. Please update as necessary. ' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 16:14:21
User closed query 'PV Query: Thank you for providing dates when EKG was done. However, the date was reported as Oct. Please confirm if the month is Oct or Aug since the event occurred in Aug. Please update as necessary. ' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 16:14:19

US3402382
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Narrative

Audit	User	Time (GMT)
Query 'PV Query: Thank you for providing dates when COVID-19 test was done. However, the date was reported as Oct. Please confirm if the month was Oct or Aug since the event occurred in AUG. Please update as necessary. ' answered with 'Updated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 15:04:44
Query 'PV Query: Thank you for providing dates when EKG was done. However, the date was reported as Oct. Please confirm if the month is Oct or Aug since the event occurred in Aug. Please update as necessary. ' answered with 'Updated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 15:04:39

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Narrative

Audit	User	Time (GMT)
User entered 'SUBJECT PRESENTED IN OFFICE 26/AUG/2020 FOR A CONVALESCENT DAY 1 VISIT. HIS PULSE WAS NOTED TO BE 139. HE ALSO STATED THAT HE THOUGHT HE WAS HAVING SYMPTOMS OF AN URINARY INFECTION. HE WAS ADVISED TO GO TO THE EMERGENCY ROOM AT THAT POINT. WHICH HE DECLINED. HE WAS GIVEN LEVOFLOXACIN 500MG PO FOR 10 DAYS. WHEN HE CAME TO LEAVE HIS DAY 3 SALIVA SAMPLE2 28OCT2020 IT WAS NOTED THAT THE PATIENT WAS NOT ANY BETTER. PATIENT STATED THAT HE WAS UNSTEADY ON HIS FEET AND HAD FALLEN PRIOR TO COMING TO DROP OFF SAMPLE. IT WAS AGAIN RECOMMENDED THAT THE SUBJECT GO TO THE ER. WHICH HE DID.DUE TO SUBJECT FALLING HE HAD A CT OF THE HEAD AND BRAIN, THAT WERE NEGATIVE. ALSO A CHEST X-RAY THAT WAS NEGATIVE. SUBJECTS BLOOD PRESSURE IN THE ER WAS 86/70 HEART RATE 134 AND A RESP RATE OF 20. SUBJECT HAS VARIOUS LABS, OF NOTE WERE CRP 14, CO2 20, BUN 36, CREATININE 1.9. IT WAS THOUGHT THAT HE HAD UROSEPSIS AND WAS STARTED ON ROCEPHIN, WHILE AWAITING URINE AND BLOOD CULTURE RESULTS WHICH WERE NEGATIVE. SUBJECT WAS ADMITTED 28AUG2020 WITH A DIAGNOSIS OF ATRIAL FLUTTER. A CONULT WITH CARDIOLOGY WAS CONDUCTED, AND PATIENT WAS STARTED ON 5 MG ELIQUIS DAILY AND WILL FOLLOW UP ON AN OUT PATIENT BASIS. COVID 19 TEST PREFORMED 26AUG2020 WITH A NEGATIVE RESULT. SUBJECTS HEART RATE HAS RETURNED TO NORMAL WITH THE HELP OF MEDICATION WHICH IS CAPTURES ON THE CONMED LOG.' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 15:04:22
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:50

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US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User opened query 'PV Query: Thank you for providing dates when COVID-19 test was done. However, the date was reported as Oct. Please confirm if the month was Oct or Aug since the event occurred in AUG. Please update as necessary. ' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 16:42:22
User opened query 'PV Query: Thank you for providing dates when EKG was done. However, the date was reported as Oct. Please confirm if the month is Oct or Aug since the event occurred in Aug. Please update as necessary. ' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 16:42:05
User closed query 'PV Query: Please provide the date COVID-19 test was performed which resulted negative.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:03:42
User closed query 'PV Query: Please provide the date EKG done which showed atypical atrial flutter with variable blockage.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:03:39

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Narrative

Audit	User	Time (GMT)
User entered 'SUBJECT PRESENTED IN OFFICE 26/AUG/2020 FOR A CONVALESCENT DAY 1 VISIT. HIS PULSE WAS NOTED TO BE 139. HE ALSO STATED THAT HE THOUGHT HE WAS HAVING SYMPTOMS OF AN URINARY INFECTION. HE WAS ADVISED TO GO TO THE EMERGENCY ROOM AT THAT POINT. WHICH HE DECLINED. HE WAS GIVEN LEVOFLOXACIN 500MG PO FOR 10 DAYS. WHEN HE CAME TO LEAVE HIS DAY 3 SALIVA SAMPLE2 28OCT2020 IT WAS NOTED THAT THE PATIENT WAS NOT ANY BETTER. PATIENT STATED THAT HE WAS UNSTEADY ON HIS FEET AND HAD FALLEN PRIOR TO COMING TO DROP OFF SAMPLE. IT WAS AGAIN RECOMMENDED THAT THE SUBJECT GO TO THE ER. WHICH HE DID.DUE TO SUBJECT FALLING HE HAD A CT OF THE HEAD AND BRAIN, THAT WERE NEGATIVE. ALSO A CHEST X-RAY THAT WAS NEGATIVE. SUBJECTS BLOOD PRESSURE IN THE ER WAS 86/70 HEART RATE 134 AND A RESP RATE OF 20. SUBJECT HAS VARIOUS LABS, OF NOTE WERE CRP 14, CO2 20, BUN 36, CREATININE 1.9. IT WAS THOUGHT THAT HE HAD UROSEPSIS AND WAS STARTED ON ROCEPHIN, WHILE AWAITING URINE AND BLOOD CULTURE RESULTS WHICH WERE NEGATIVE. SUBJECT WAS ADMITTED 28OCT2020 WITH A DIAGNOSIS OF ATRIAL FLUTTER. A CONULT WITH CARDIOLOGY WAS CONDUCTED, AND PATIENT WAS STARTED ON 5 MG ELIQUIS DAILY AND WILL FOLLOW UP ON AN OUT PATIENT BASIS. COVID 19 TEST PREFORMED 26OCT2020 WITH A NEGATIVE RESULT. Subjects Heart rate has returned to normal with the help of medication which is captures on the ConMed log.' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 12:44:37
Query 'PV Query: Please provide the date COVID-19 test was performed which resulted negative.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	29 Oct 2020 21:34:07

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US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide the date EKG done which showed atypical atrial flutter with variable blockage.' answered with 'UPdated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	29 Oct 2020 21:34:02
User entered 'SUBJECT PRESENTED IN OFFICE 26/AUG/2020 FOR A CONVALESCENT DAY 1 VISIT. HIS PULSE WAS NOTED TO BE 139. HE ALSO STATED THAT HE THOUGHT HE WAS HAVING SYMPTOMS OF AN URINARY INFECTION. HE WAS ADVISED TO GO TO THE EMERGENCY ROOM AT THAT POINT. WHICH HE DECLINED. HE WAS GIVEN LEVOFLOXACIN 500MG PO FOR 10 DAYS. WHEN HE CAME TO LEAVE HIS DAY 3 SALIVA SAMPLE2 28OCT2020 IT WAS NOTED THAT THE PATIENT WAS NOT ANY BETTER. PATIENT STATED THAT HE WAS UNSTEADY ON HIS FEET AND HAD FALLEN PRIOR TO COMING TO DROP OFF SAMPLE. IT WAS AGAIN RECOMMENDED THAT THE SUBJECT GO TO THE ER. WHICH HE DID.DUE TO SUBJECT FALLING HE HAD A CT OF THE HEAD AND BRAIN, THAT WERE NEGATIVE. ALSO A CHEST X-RAY THAT WAS NEGATIVE. SUBJECTS BLOOD PRESSURE IN THE ER WAS 86/70 HEART RATE 134 AND A RESP RATE OF 20. SUBJECT HAS VARIOUS LABS, OF NOTE WERE CRP 14, CO2 20, BUN 36, CREATININE 1.9. IT WAS THOUGHT THAT HE HAD UROSEPSIS AND WAS STARTED ON ROCEPHIN, WHILE AWAITING URINE AND BLOOD CULTURE RESULTS WHICH WERE NEGATIVE. SUBJECT WAS ADMITTED 28OCT2020 WITH A DIAGNOSIS OF ATRIAL FLUTTER. A CONULT WITH CARDIOLOGY WAS CONDUCTED, AND PATIENT WAS STARTED ON 5 MG ELIQUIS DAILY AND WILL FOLLOW UP ON AN OUT PATIENT BASIS. Covid 19 Test Preformed 26OCT2020 with a negative result' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	29 Oct 2020 21:33:27

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Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the date COVID-19 test was performed which resulted negative.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:21:17
User opened query 'PV Query: Please provide the date EKG done which showed atypical atrial flutter with variable blockage.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:21:10
User closed query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 18:11:29
Query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 17:55:12
User opened query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 08:31:52
User closed query 'PV Query: Please provide results of any diagnostic tests performed (i.e. EKG, echocardiogram, etc.).' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 17:21:09
Query 'PV Query: Please provide results of any diagnostic tests performed (i.e. EKG, echocardiogram, etc.).' answered with 'EKG DONE SHOWED ATYPICAL ATRIAL FLUTTER WITH VARIABE BLOCKAGE' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 18:30:41
User closed query 'Did the subject ever experience any arrhythmia or other cardiac event? Please provide a detailed cardiac history.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:29:16
User closed query 'PV Query: Please provide repeat vital signs at discharge.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:29:14
User closed query 'PV Query: Please provide the cardiologist assessment from the consultation.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:29:12
User closed query 'PV Query: Was the subject in normal sinus rhythm at discharge? If so, was this confirmed by EKG?' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:29:09

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Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Did the patient require any treatment for hypotension or antiarrhythmics, etc. for atrial flutter? If so, please add to concomitant medication eCRF.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:29:06
User closed query 'PV query: The subject was prescribed levofloxacin after UTI was suspected, but the cultures were done after next visit to the ER. Did the subject take levofloxacin tablets before the cultures?' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:29:03
User closed query 'PV query: Did the subject have fever before the event and after dose 1? If yes, what severity?' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:28:59
User closed query 'PV Query: The event was reported as resolved with sequelae. Please provide the sequelae.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:28:39
User closed query 'PV Query: Please confirm if an EKG was done on 26 Aug 2020, when the subject's heart rate was 136. If so, please provide results. If atrial flutter was confirmed on this date, please consider amending event start date.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:28:36
Query 'PV Query: Please provide the cardiologist assessment from the consultation.' answered with 'SUBJECT HAS NOT HAD APPOINTMENT YET' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 01:38:32
Query 'Did the subject ever experience any arrhythmia or other cardiac event? Please provide a detailed cardiac history.' answered with 'INFORMATION NOT AVAILABLE' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 01:37:52
Query 'PV Query: Please provide repeat vital signs at discharge.' answered with 'information no available' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 01:37:27
Query 'PV Query: Was the subject in normal sinus rhythm at discharge? If so, was this confirmed by EKG?' answered with 'information not avaiable' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 01:36:57
Query 'PV Query: Did the patient require any treatment for hypotension or antiarrhythmics, etc. for atrial flutter? If so, please add to concomitant medication eCRF.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 01:35:21

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Folder: Adverse Events
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Narrative

Audit	User	Time (GMT)
Query 'PV Query: The event was reported as resolved with sequelae. Please provide the sequelae.' answered with 'subject is following up with cardiologist' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 01:35:07
Query 'PV query: The subject was prescribed levofloxacin after UTI was suspected, but the cultures were done after next visit to the ER. Did the subject take levofloxacin tablets before the cultures?' answered with 'yes' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 01:33:24
Query 'PV query: Did the subject have fever before the event and after dose 1? If yes, what severity?' answered with 'no' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 01:33:03
Query 'PV Query: Please confirm if an EKG was done on 26 Aug 2020, when the subject's heart rate was 136. If so, please provide results. If atrial flutter was confirmed on this date, please consider amending event start date.' answered with 'ECG was not done in office' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 01:32:46
User opened query 'Did the subject ever experience any arrhythmia or other cardiac event? Please provide a detailed cardiac history.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:46:58
User opened query 'PV Query: Please provide repeat vital signs at discharge.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:45:58
User opened query 'PV Query: Please provide the cardiologist assessment from the consultation.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:45:31
User opened query 'PV Query: Was the subject in normal sinus rhythm at discharge? If so, was this confirmed by EKG?' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:45:05
User opened query 'PV Query: Please provide results of any diagnostic tests performed (i.e. EKG, echocardiogram, etc.).' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:44:43
User opened query 'PV Query: Did the patient require any treatment for hypotension or antiarrhythmics, etc. for atrial flutter? If so, please add to concomitant medication eCRF.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:44:33
User opened query 'PV query: The subject was prescribed levofloxacin after UTI was suspected, but the cultures were done after next visit to the ER. Did the subject take levofloxacin tablets before the cultures?' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:44:17

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Narrative

Audit	User	Time (GMT)
User opened query 'PV query: Did the subject have fever before the event and after dose 1? If yes, what severity?' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:43:54
User opened query 'PV Query: The event was reported as resolved with sequelae. Please provide the sequelae.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:42:51
User opened query 'PV Query: Please confirm if an EKG was done on 26 Aug 2020, when the subject's heart rate was 136. If so, please provide results. If atrial flutter was confirmed on this date, please consider amending event start date.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:42:29
User entered 'Subject presented in office 26/Aug/2020 for a convalescent day 1 visit. His pulse was noted to be 139. He also stated that he thought he was having symptoms of an urinary infection. He was advised to go to the emergency room at that point. Which he declined. He was given levofloxacin 500mg po for 10 days. When he came to leave his day 3 saliva sample it was noted that the patient was not any better. Patient stated that he was unsteady on his feet and had fallen prior to coming to drop off sample. It was again recommended that the subject go to the ER. Which he did.Due to subject falling he had a CT of the head and brain, that were negative. Also a chest x-ray that was negative. Subjects blood pressure in the Er was 86/70 heart rate 134 and a resp rate of 20. Subject has various labs, of note were CRP 14, CO2 20, Bun 36, Creatinine 1.9. It was thought that he had Urosepsis and was started on Rocephin, while awaiting urine and blood culture results which were negative. Subject was admitted with a diagnosis of atrial flutter. A conult with cardiology was conducted, and patient was started on 5 mg Eliquis daily and will follow up on an out patient basis.'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

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Folder: Adverse Events
Form: Adverse Events (1)
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Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:29:09
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	02 Sep 2020 11:02:13

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39

FDA-CBER-2022-1614-1770343

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
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)	03 Nov 2020 16:33:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 16:33:43
Data point term sent to Coder	System	02 Nov 2020 13:09:34
User entered 'URINARY TRACT INFECTION'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

FDA-CBER-2022-1614-1770346

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '26 Aug 2020'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered empty.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User entered empty.	System	02 Nov 2020 13:09:09

FDA-CBER-2022-1614-1770350

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '6 Sep 2020'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

FDA-CBER-2022-1614-1770352

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered empty.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User entered empty.	System	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered empty.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered empty.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered empty.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered empty.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'Not Related (NOT RELATED)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 04:14:20
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:11
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 13:43:33
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 13:43:27
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 13:43:27
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:22:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'Not Applicable (NOT APPLICABLE)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'None (NONE)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '1'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered empty.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered empty.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User entered '0'	System	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39
User entered '1'	System	02 Nov 2020 13:09:09

US3402382
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:29:09
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:18:39

FDA-CBER-2022-1614-1770378

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:49
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:51
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)	08 Apr 2021 17:41:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 17:41:55
Data point term sent to Coder	System	08 Apr 2021 17:40:27
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	08 Apr 2021 17:40:04
Data point term sent to Coder	System	07 Apr 2021 20:09:45
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	07 Apr 2021 20:08:49
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)	07 Apr 2021 18:42:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 18:42:45
Data point term sent to Coder	System	07 Apr 2021 18:41:18
User entered 'FATIGUE'	Traci Hull (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:52
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:56
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered '18 Aug 2020'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:57
User closed query 'Per CDM re-query: Per previous query, as the AE did not start within 24 hours of dosing, the start time of 00:00 is not required. Please remove the start time and leave the field blank.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 04:10:42
Query 'Per CDM re-query: Per previous query, as the AE did not start within 24 hours of dosing, the start time of 00:00 is not required. Please remove the start time and leave the field blank.' answered with 'updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	14 Apr 2021 16:33:04
Signature has been broken.	Tammy Kohn (b) (4) (b) (4)	14 Apr 2021 16:32:54
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	14 Apr 2021 16:32:54
User opened query 'Per CDM re-query: Per previous query, as the AE did not start within 24 hours of dosing, the start time of 00:00 is not required. Please remove the start time and leave the field blank.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 14:57:20
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4), (b) (6)	14 Apr 2021 14:55:37
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'CORRECT AS IS' (Site from System).	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:41:29
User entered '00:00' reason for change: Data Entry Error	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:41:02

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	07 Apr 2021 18:40:44
User entered '06:00'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
User entered empty.	System	14 Apr 2021 16:32:54
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered '18 Aug 2020 00:00'	System	07 Apr 2021 18:41:02
User entered '18 Aug 2020 06:00'	System	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:01
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
User entered '24 Aug 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:42:38
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered '23 Aug 2020'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:03
User closed query 'Per CDM re-query: Per previous query, as the AE did not start within 24 hours of dosing, the end time of 00:00 is not required. Please remove the end time and leave the field blank.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 04:10:44
Query 'Per CDM re-query: Per previous query, as the AE did not start within 24 hours of dosing, the end time of 00:00 is not required. Please remove the end time and leave the field blank.' answered with 'updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	14 Apr 2021 16:33:06
Signature has been broken.	Tammy Kohn (b) (4) (b) (4)	14 Apr 2021 16:32:54
User entered empty; reason for change New Information	Tammy Kohn (b) (4) (b) (4)	14 Apr 2021 16:32:54
User opened query 'Per CDM re-query: Per previous query, as the AE did not start within 24 hours of dosing, the end time of 00:00 is not required. Please remove the end time and leave the field blank.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 14:57:43
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4), (b) (6)	14 Apr 2021 14:55:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'CORRECT AS IS' (Site from System).	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:41:58
User entered '00:00' reason for change: New Information	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:41:49

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User entered '10:00' reason for change: Data Entry Error	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:41:02
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	07 Apr 2021 18:40:44
User entered '15:00'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
User entered empty.	System	14 Apr 2021 16:32:54
User entered '24 Aug 2020 00:00'	System	08 Apr 2021 17:42:38
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered '23 Aug 2020 00:00'	System	07 Apr 2021 18:41:49
User entered '23 Aug 2020 10:00'	System	07 Apr 2021 18:41:02
User entered '23 Aug 2020 15:00'	System	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:09
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:18
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered '0'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:23
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered '0'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered '0'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:27
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered empty.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered empty.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:37
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered empty.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered empty.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered '0'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered '0'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

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US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:45
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered '0'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered 'Related (RELATED)'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	03 May 2021 22:58:39
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
User closed query 'Per CDM: Per CCGs, relationship to study procedure should be 'Not related'. Please review and update appropriately, else clarify.' (Site from DM).	(b) (4), (b) (6)	01 May 2021 08:30:50
Query 'Per CDM: Per CCGs, relationship to study procedure should be 'Not related'. Please review and update appropriately, else clarify.' answered with 'PER QUERY UPDATED ACTION TO NOT APPLICABLE' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	30 Apr 2021 13:48:36
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	30 Apr 2021 13:48:00
Signature has been broken.	Tammy Kohn (b) (4) (b) (4)	30 Apr 2021 13:48:00
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	30 Apr 2021 13:48:00
User opened query 'Per CDM: Per CCGs, relationship to study procedure should be 'Not related'. Please review and update appropriately, else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 06:56:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered 'Related (RELATED)'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

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US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	03 May 2021 22:58:39
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	30 Apr 2021 13:48:00
Signature has been broken.	Tammy Kohn (b) (4) (b) (4)	30 Apr 2021 13:48:00
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	30 Apr 2021 13:48:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered 'None (NONE)'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:55
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered '1'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:56
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered '0'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:58
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered '0'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered empty.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:03
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered empty.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 18:40:44

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US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered '0'	System	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49
User entered '0'	System	07 Apr 2021 18:40:44

US3402382
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:29:09
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:30
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 17:40:04
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	07 Apr 2021 20:08:49

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 09 Jun 2021 17:29:09
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:52
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
User closed query 'Per SAE summary - subject received Levofloxacin for AE UTI and Eliquis for AE Atrial Flutter - medications were added to ConMeds but fields inactivated. Please provide a reason for this. Also per source ConMeds log - Keflex 500mg PO, QD was given from 26 Aug 2020 - 06 Sep 2020 for UTI - Please add this to ConMeds log in EDC.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:40:09
Query 'Per SAE summary - subject received Levofloxacin for AE UTI and Eliquis for AE Atrial Flutter - medications were added to ConMeds but fields inactivated. Please provide a reason for this. Also per source ConMeds log - Keflex 500mg PO, QD was given from 26 Aug 2020 - 06 Sep 2020 for UTI - Please add this to ConMeds log in EDC.' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:55
User opened query 'Per SAE summary - subject received Levofloxacin for AE UTI and Eliquis for AE Atrial Flutter - medications were added to ConMeds but fields inactivated. Please provide a reason for this. Also per source ConMeds log - Keflex 500mg PO, QD was given from 26 Aug 2020 - 06 Sep 2020 for UTI - Please add this to ConMeds log in EDC.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:33:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:35
User closed query 'Per ETRTR: Please add medication dosed for SAE Atrial Flutter, thanks.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:28:34
Query 'Per ETRTR: Please add medication dosed for SAE Atrial Flutter, thanks.' answered with 'will update' (Site from CRA).	Jennifer Molstead (b) (4) (b) (4)	16 Sep 2020 14:58:38

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US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:29:09

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User opened query 'Per ETRTR: Please add medication dosed for SAE Atrial Flutter, thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Sep 2020 14:59:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:54
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:04:11

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIMEPIRIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:52:22
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 Aug 2020 20:52:22
Data point term sent to Coder	System	17 Aug 2020 20:51:09
User entered 'glimepiride'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:50:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:29:09
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:50:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:29:09
Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'DIABETES TYPE 2'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:50:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:29:09
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '2'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:50:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:29:09
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:50:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:29:09
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:50:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:29:09
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:50:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:29:09
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:50:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:29:09
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:50:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:29:09
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:50:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:29:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '21 Jul 2020'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:50:13

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US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:50:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:29:09
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:50:13

FDA-CBER-2022-1614-1770431

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:29:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:50:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:29:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:50:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:29:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:50:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:50:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 20:50:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 18:16:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 18:16:41
Data point term sent to Coder	System	08 Jan 2021 18:15:29
Coding entries removed.	Tammy Kohn (b) (4) (b) (4)	08 Jan 2021 18:15:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 14:05:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 14:05:28
Data point term sent to Coder	System	23 Oct 2020 14:04:49
Coding entries removed.	Tammy Kohn (b) (4) (b) (4)	23 Oct 2020 14:03:58

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:53:14
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 Aug 2020 20:53:14
Data point term sent to Coder	System	17 Aug 2020 20:52:12
User entered 'ASPIRIN'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:51:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:29:09
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:51:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:29:09
Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:27:06
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 16:33:53
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	08 Jan 2021 18:15:38
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	08 Jan 2021 18:15:28
User entered 'HEART ATTACK PREVENTION' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	08 Jan 2021 18:15:28
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 15:26:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User closed query 'Per CDM re-query: Previous response noted, however the Indication is still recorded as 'CARDIAC'. Please review and update the Indication to reflect the underlying medical condition.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 11:51:03
Query 'Per CDM re-query: Previous response noted, however the Indication is still recorded as 'CARDIAC'. Please review and update the Indication to reflect the underlying medical condition.' answered with 'HEART ATTACK' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Oct 2020 14:04:07
User entered 'HEART ATTACK' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Oct 2020 14:03:58

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:29:09
Indication

Audit	User	Time (GMT)
User opened query 'Per CDM re-query: Previous response noted, however the Indication is still recorded as 'CARDIAC'. Please review and update the Indication to reflect the underlying medical condition.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 12:25:41
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 15:42:02
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Update eCRF as appropriate.' answered with 'HEART ATTACK ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	21 Sep 2020 20:43:06
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:03:49
User entered 'CARDIAC'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:51:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:29:09
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '81'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:51:14

FDA-CBER-2022-1614-1770442

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:29:09
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:51:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:29:09
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:51:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:29:09
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:51:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:29:09
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:51:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:29:09
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:51:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:29:09
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:51:14

FDA-CBER-2022-1614-1770448

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:29:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
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).	(b) (4), (b) (6)	18 Aug 2020 05:21:53
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 'ONGOING' (Site from System).	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:04:43
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	17 Aug 2020 20:51:14
User entered '25 Aug 2008'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:51:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:51:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:29:09
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:51:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:29:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:51:14

FDA-CBER-2022-1614-1770452

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:29:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:51:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:29:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:51:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:51:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 20:51:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: SILDENAFIL, PRODUCTSYNONYM: VIAGRA [SILDENAFIL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:57:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:57:16
Data point term sent to Coder	System	17 Aug 2020 20:52:12
User entered 'VIAGARA'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:52:08

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:29:09
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:52:08

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:29:09
Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'ERECTILE DYSFUNCTION'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:52:08

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:29:09
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '100'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:52:08

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:29:09
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:52:08

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:29:09
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:52:08

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:29:09
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'as needed (PRN)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:52:08

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:29:09
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:52:08

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:29:09
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:52:08

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:29:09
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:52:08

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:29:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
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).	(b) (4), (b) (6)	18 Aug 2020 05:25:00
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 'ONGOING' (Site from System).	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:04:37
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	17 Aug 2020 20:52:08
User entered '25 Aug 2008'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:52:08

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:52:08

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:29:09
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:52:08

FDA-CBER-2022-1614-1770469

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:29:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:52:08

FDA-CBER-2022-1614-1770470

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:29:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:52:08

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:29:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 20:52:08

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 20:52:08

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 20:52:08

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:54:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:54:15
Data point term sent to Coder	System	17 Aug 2020 20:53:15
User entered 'METOPROLOL ER'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:53:02

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:29:09
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:53:02

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:29:09
Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'HYPERTENSION'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:53:02

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:29:09
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '50'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:53:02

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:29:09
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:53:02

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:29:09
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:53:02

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:29:09
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:53:02

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:29:09
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:53:02

FDA-CBER-2022-1614-1770482

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:29:09
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:53:02

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:29:09
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:53:02

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:29:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
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).	(b) (4), (b) (6)	18 Aug 2020 05:20:07
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 'ONGOING' (Site from System).	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:04:29
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	17 Aug 2020 20:53:02
User entered '25 Apr 2008'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:53:02

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:53:02

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:29:09
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:53:02

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:29:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:53:02

FDA-CBER-2022-1614-1770488

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:29:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:53:02

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:29:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:53:02

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:53:02

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 20:53:02

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:55:16
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 Aug 2020 20:55:16
Data point term sent to Coder	System	17 Aug 2020 20:54:16
User entered 'ATORVASTATIN'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:54:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:29:09
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:54:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:29:09
Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'HYPERLIPIDEMIA'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:54:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:29:09
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '40'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:54:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:29:09
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:54:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:29:09
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:54:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:29:09
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:54:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:29:09
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:54:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:29:09
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:54:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:29:09
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:54:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:29:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
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).	(b) (4), (b) (6)	18 Aug 2020 05:20:33
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 'ONGOING' (Site from System).	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:04:22
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	17 Aug 2020 20:54:04
User entered '10 Feb 2015'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:54:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:54:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:29:09
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:54:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:29:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:54:04

FDA-CBER-2022-1614-1770506

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:29:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:54:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:29:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:54:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:54:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 20:54:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:56:18
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 Aug 2020 20:56:18
Data point term sent to Coder	System	17 Aug 2020 20:55:17
User entered 'tamsulosin'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:55:06

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:29:09
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:55:06

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:29:09
Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'BENIGN PROSTATIC HYPERTROPHY'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:55:06

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:29:09
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0.4'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:55:06

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:29:09
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:55:06

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:29:09
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:55:06

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:29:09
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:55:06

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:29:09
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:55:06

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:29:09
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:55:06

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:29:09
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:55:06

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:29:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
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).	(b) (4), (b) (6)	18 Aug 2020 05:20:55
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 'ONGOING' (Site from System).	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:04:16
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	17 Aug 2020 20:55:06
User entered '01 Sep 2017'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:55:06

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:55:06

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:29:09
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:55:06

FDA-CBER-2022-1614-1770523

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:29:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:55:06

FDA-CBER-2022-1614-1770524

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:29:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:55:06

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:29:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:55:06

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:55:06

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 20:55:06

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: FEBUXOSTAT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 00:28:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 00:28:20
Data point term sent to Coder	System	17 Aug 2020 20:57:20
User entered 'febuxostat'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:56:26

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:29:09
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:56:26

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:29:09
Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User closed query 'Per DM CLR: Please update the indication to reflect the location of GOUT. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 15:42:12
Query 'Per DM CLR: Please update the indication to reflect the location of GOUT. Please reconcile with Med History eCRF as appropriate. ' answered with 'LEFT BIG TOE' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	22 Sep 2020 20:28:57
User opened query 'Per DM CLR: Please update the indication to reflect the location of GOUT. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:04:19
User entered 'GOUT'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:56:26

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:29:09
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '40'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:56:26

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:29:09
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:56:26

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:29:09
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:56:26

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:29:09
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:56:26

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:29:09
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:56:26

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:29:09
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:56:26

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:29:09
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:56:26

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:29:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
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).	(b) (4), (b) (6)	18 Aug 2020 05:26:27
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 'ONGOING' (Site from System).	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:04:09
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	17 Aug 2020 20:56:26
User entered '25 Oct 2017'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:56:26

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:56:26

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:29:09
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:56:26

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:29:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:56:26

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US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:29:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:56:26

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:29:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:56:26

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:56:26

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 20:56:26

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 12:00:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 12:00:43
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
Data point term sent to Coder	System	11 Nov 2020 16:28:11
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	11 Nov 2020 16:27:58
Coding entries removed.	Tammy Kohn (b) (4) (b) (4)	11 Nov 2020 16:27:58
User entered 'VOLTAREN 1%' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	11 Nov 2020 16:27:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:53:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:53:26
Data point term sent to Coder	System	17 Aug 2020 20:57:21

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
User entered 'VOLTAREN'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:16

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:29:09
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:16

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:29:09
Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'OSTEOARTHRITIS BILATERAL HIPS'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:16

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:29:09
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:27:06
DataPoint Un-verified.	Tammy Kohn (b) (4)	08 Jan 2021 18:21:45
User entered '2' reason for change: Data Entry Error	(b) (4) Tammy Kohn (b) (4)	08 Jan 2021 18:21:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:56:30
User closed query 'Per source dose is listed as 1%. Please enter 1 for dose, other for unit and % for other field. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 21:56:27
Query 'Per source dose is listed as 1%. Please enter 1 for dose, other for unit and % for other field. Please verify and update accordingly.' answered with 'DATA UPDATED' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	11 Nov 2020 16:32:43
DataPoint Un-verified.	Tammy Kohn (b) (4)	11 Nov 2020 16:32:34
User entered '1' reason for change: Data Entry Error	(b) (4) Tammy Kohn (b) (4)	11 Nov 2020 16:32:34
User opened query 'Per source dose is listed as 1%. Please enter 1 for dose, other for unit and % for other field. Please verify and update accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:35:18
User closed query 'Per source dose is listed as 1%. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:35:18
Query 'Per source dose is listed as 1%. Please verify and update accordingly. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:38:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User opened query 'Per source dose is listed as 1%. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:24:09

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:09

Dose per administration

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 18:43:21
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Sep 2020 11:34:03
User entered '100' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Sep 2020 11:33:49
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:04:41
User entered '1'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:16

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:29:09
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:27:06
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	08 Jan 2021 18:21:45
User entered 'g (g)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	08 Jan 2021 18:21:45
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	11 Nov 2020 16:32:34
User entered 'Other (OTHER)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	11 Nov 2020 16:32:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'g (g)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Sep 2020 11:33:49
User entered 'Other (OTHER)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:16

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:29:09
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:27:06
User closed query 'Per DM CLR: Please review Dose and Dose Unit and consider recording the number of applications instead (e.g. Dose = 1; Unit = Application). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 16:37:11
Query 'Per DM CLR: Please review Dose and Dose Unit and consider recording the number of applications instead (e.g. Dose = 1; Unit = Application). Review and amend as appropriate.' answered with 'DATA UPDATED 2 GRAMS PER DAY TO EFFECTED AREA' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	08 Jan 2021 18:23:10
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	08 Jan 2021 18:21:45
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	08 Jan 2021 18:21:45
User opened query 'Per DM CLR: Please review Dose and Dose Unit and consider recording the number of applications instead (e.g. Dose = 1; Unit = Application). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 15:28:24
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	11 Nov 2020 16:32:34
User entered '%' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	11 Nov 2020 16:32:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Sep 2020 11:33:49
User entered '%'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:16

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:29:09
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:16

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:29:09
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:16

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:29:09
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Topical (TOPICAL)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:16

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:29:09
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:16

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US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:29:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
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).	(b) (4), (b) (6)	18 Aug 2020 05:25:52
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 'ONGOING' (Site from System).	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:04:02
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	17 Aug 2020 20:57:16
User entered '25 Apr 2018'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:16

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:16

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:29:09
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:16

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:29:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:16

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US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:29:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:16

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:29:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:57:16

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:57:16

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 20:57:16

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE, PRODUCTSYNONYM: OZEMPIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 13:06:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 13:06:32
Data point term sent to Coder	System	19 Oct 2020 13:05:53
Coding entries removed.	Tammy Kohn (b) (4) (b) (4)	19 Oct 2020 13:05:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE, PRODUCTSYNONYM: OZEMPIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 11:37:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 11:37:52
Data point term sent to Coder	System	23 Sep 2020 11:37:11
Coding entries removed.	Tammy Kohn (b) (4) (b) (4)	23 Sep 2020 11:37:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE, PRODUCTSYNONYM: OZEMPIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:59:21

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
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 Aug 2020 20:59:21
Data point term sent to Coder	System	17 Aug 2020 20:58:25
User entered 'OZEMPIC'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:53

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:29:09
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:53

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:29:09
Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'DIABETES TYPE 2'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:53

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:29:09
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '1'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:53

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:29:09
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:53

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:29:09
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:53

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:29:09
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:27:06
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 06:32:30
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:11:19
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:11:11
User entered 'every week (QS)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:11:11
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 11:40:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:53

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:29:09
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:53

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:29:09
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
User closed query 'Per source route of administration is PO. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:36:21
Query 'Per source route of administration is PO. Please verify and update accordingly. ' answered with 'source updated' (Site from CRA).	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:39:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User opened query 'Per source route of administration is PO. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:25:11
User closed query 'Per DM CLR-RQ: Updated route to INTRAMUSCULAR. However, this route is also not an expected/usual route for this CM. Please review and verify source documents and update if applicable. Otherwise, provide confirmation/clarification.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 11:50:50
Query 'Per DM CLR-RQ: Updated route to INTRAMUSCULAR. However, this route is also not an expected/usual route for this CM. Please review and verify source documents and update if applicable. Otherwise, provide confirmation/clarification.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	19 Oct 2020 13:05:24
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Oct 2020 13:05:18
User opened query 'Per DM CLR-RQ: Updated route to INTRAMUSCULAR. However, this route is also not an expected/usual route for this CM. Please review and verify source documents and update if applicable. Otherwise, provide confirmation/clarification.' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 15:21:31
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 18:43:33

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:29:09

Route of administration

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Sep 2020 11:37:12
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Sep 2020 11:37:02
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:05:22
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:53

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:29:09
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:53

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US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:29:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
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).	(b) (4), (b) (6)	18 Aug 2020 05:25:28
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 'ONGOING' (Site from System).	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:54
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	17 Aug 2020 20:57:53
User entered '05 Nov 2018'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:53

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:53

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:29:09
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:53

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:29:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:53

FDA-CBER-2022-1614-1770582

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:29:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:53

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:29:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:57:53

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:57:53

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '803 (803)'	System	16 Nov 2020 19:11:11
User entered '804 (804)'	System	17 Aug 2020 20:57:53

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:59:22
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 Aug 2020 20:59:22
Data point term sent to Coder	System	17 Aug 2020 20:58:25
User entered 'DULOXETINE'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:58:24

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:29:09
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:58:24

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:29:09
Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'ANXIETY'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:58:24

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:29:09
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '60'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:58:24

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:29:09
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:58:24

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:29:09
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:58:24

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:29:09
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:58:24

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:29:09
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:58:24

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:29:09
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:58:24

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:29:09
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:58:24

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US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:29:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
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).	(b) (4), (b) (6)	18 Aug 2020 05:26:08
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 'ONGOING' (Site from System).	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:46
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 20:58:24
User entered '05 Nov 2018'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:58:24

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:58:24

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:29:09
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:58:24

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:29:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:58:24

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US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:29:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:58:24

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:29:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:58:24

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:58:24

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 20:58:24

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 21:00:22
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 Aug 2020 21:00:22
Data point term sent to Coder	System	17 Aug 2020 20:59:25
User entered 'JARDIANCE'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:59:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:29:09
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:59:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:29:09
Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'DIABETES TYPE 2'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:59:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:29:09
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '25'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:59:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:29:09
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:59:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:29:09
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:59:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:29:09
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:59:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:29:09
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:59:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:29:09
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:59:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:29:09
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:59:14

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US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:29:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
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).	(b) (4), (b) (6)	18 Aug 2020 05:26:40
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 'ONGOING' (Site from System).	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:39
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	17 Aug 2020 20:59:14
User entered '18 Apr 2017'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:59:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:59:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:29:09
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:59:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:29:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:59:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:29:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:59:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:29:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:59:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:59:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 20:59:14

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 21:01:27
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 Aug 2020 21:01:27
Data point term sent to Coder	System	17 Aug 2020 21:00:28
User entered 'hydrocodone'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:29:09
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:29:09
Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User closed query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 15:42:30
Query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS. Please reconcile with Med History eCRF as appropriate. ' answered with 'OSTEOARTHRITIS IS THROUGH OUT THE BODY' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Sep 2020 11:38:06
User opened query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:05:51
User entered 'OSTEOARTHRITIS'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:29:09
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '5'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:29:09
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:29:09
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:29:09
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:29:09
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:29:09
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:29:09
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:29:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
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).	(b) (4), (b) (6)	18 Aug 2020 05:21:30
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 'ONGOING' (Site from System).	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:33
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	17 Aug 2020 21:00:04
User entered '31 Oct 2019'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:29:09
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:29:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:04

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US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:29:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:29:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 21:00:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 21:00:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 21:00:04

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 21:02:16
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 Aug 2020 21:02:16
Data point term sent to Coder	System	17 Aug 2020 21:01:30
User entered 'COLACE'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:41

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:29:09
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:41

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:29:09
Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'CONSTIPATION'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:41

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:29:09
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '100'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:41

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:29:09
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:41

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:29:09
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:41

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:29:09
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:41

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:29:09
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:41

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:29:09
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:41

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:29:09
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:41

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:29:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
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).	(b) (4), (b) (6)	18 Aug 2020 05:27:01
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 'ONGOING' (Site from System).	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:26
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	17 Aug 2020 21:00:41
User entered '04 Nov 2019'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:41

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:41

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:29:09
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:41

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:29:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:41

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:29:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:41

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:29:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 21:00:41

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 21:00:41

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 21:00:41

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:12:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:12:26
Data point term sent to Coder	System	17 Aug 2020 21:03:33
User entered 'LANTUS SOLOSTAR'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:29:09
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:29:09
Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'TYPE 2 DIABETES'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:29:09
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '100'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:29:09
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Other (OTHER)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:29:09
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'UNITS'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:29:09
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:29:09
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:29:09
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Subcutaneous (SUBCUTANEOUS)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:29:09
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:13

FDA-CBER-2022-1614-1770668

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:29:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
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).	(b) (4), (b) (6)	18 Aug 2020 05:27:15
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 'ONGOING' (Site from System).	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:19
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	17 Aug 2020 21:03:13
User entered '04 Nov 2019'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:29:09
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:29:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:13

FDA-CBER-2022-1614-1770672

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:29:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:03:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:29:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 21:03:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 21:03:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 21:03:13

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 19:56:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 19:56:51
Data point term sent to Coder	System	16 Nov 2020 19:56:23
Coding entries removed.	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:55:39
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:41:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:41:43
Data point term sent to Coder	System	10 Nov 2020 21:41:16
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:24
Data point term sent to Coder	System	02 Nov 2020 13:06:30
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:05:57

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 17:59:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 17:59:32
Data point term sent to Coder	System	01 Oct 2020 17:57:32
User entered 'ELIQUIS'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 17:56:35

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 17:29:09
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:05:57
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 17:56:35

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 17:29:09
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 06:33:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:03:48
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match. ' answered with 'DATA UPDATED ALREADY AN AE' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:55:48
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:55:39
User entered 'ATRIAL FIBRILLATION' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:55:39
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 11:39:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:05:57
User entered 'anticoagulant medication'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 17:56:35

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 17:29:09
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:05:57
User entered '5'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 17:56:35

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 17:29:09
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:05:57
User entered 'mg (mg)'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 17:56:35

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 17:29:09
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:05:57
User entered empty.	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 17:56:35

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 17:29:09
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:05:57
User entered 'once daily (QD)'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 17:56:35

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 17:29:09
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:05:57
User entered empty.	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 17:56:35

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 17:29:09
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:05:57
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 17:56:35

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 17:29:09
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:05:57
User entered empty.	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 17:56:35

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 17:29:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:05:57
User entered '28 Aug 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 17:58:26
User entered '16 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 17:56:35

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:05:57
User entered '0'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 17:56:35

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 17:29:09
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:27:06
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 16:36:12
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	08 Jan 2021 18:26:08
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	08 Jan 2021 18:26:03
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	08 Jan 2021 18:26:03
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 15:30:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:05:57
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 17:56:35

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 17:29:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:27:06
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	08 Jan 2021 18:26:03
User entered '01 Sep 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	08 Jan 2021 18:26:03
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:05:57
User entered empty.	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 17:56:35

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 17:29:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:10
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:27:06
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 16:36:18
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	08 Jan 2021 18:25:07
DataPoint Un-verified.	Tammy Kohn (b) (4)	08 Jan 2021 18:25:02
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	08 Jan 2021 18:25:02
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 15:29:15

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 17:29:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:03:57
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:55:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:55:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:05:57
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 17:56:35

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 17:29:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:10
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:05:57
User entered '1'	System	01 Oct 2020 17:56:35

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:10
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:05:57
User entered '1'	System	01 Oct 2020 17:56:35

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:10
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:05:57
User entered '804 (804)'	System	01 Oct 2020 17:56:35

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:15
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:49:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:49:54
Data point term sent to Coder	System	16 Nov 2020 19:55:22
Coding entries removed.	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:54:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:41:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:41:41
Data point term sent to Coder	System	10 Nov 2020 21:41:16
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:29
Data point term sent to Coder	System	02 Nov 2020 13:06:30
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:06:03

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US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:09

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 22:52:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 22:52:51
Data point term sent to Coder	System	01 Oct 2020 18:01:41
User entered 'LEVOFLOXACIN'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 18:00:59

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 17:29:09
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:15
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:06:03
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 18:00:59

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 17:29:09
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:15
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 06:33:51
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:04:05
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'DATA UPDATED THIS IS ALREADY AN AE DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:54:46
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:54:30
User entered 'URINARY TRACT INFECTION BACTERIA' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:54:30
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 11:40:13
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:06:03
User entered 'bacteria infection'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 18:00:59

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 17:29:09
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:15
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:06:03
User entered '500'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 18:00:59

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 17:29:09
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:15
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:06:03
User entered 'mg (mg)'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 18:00:59

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 17:29:09
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:15
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:06:03
User entered empty.	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 18:00:59

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 17:29:09
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:15
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:06:03
User entered 'once daily (QD)'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 18:00:59

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 17:29:09
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:15
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:06:03
User entered empty.	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 18:00:59

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 17:29:09
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:15
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:06:03
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 18:00:59

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 17:29:09
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:15
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:06:03
User entered empty.	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 18:00:59

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 17:29:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:15
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:06:03
User entered '28 Aug 2020'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 18:00:59

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:15
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:06:03
User entered '0'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 18:00:59

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 17:29:09
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:15
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:06:03
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 18:00:59

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 17:29:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:15
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
User entered '08 Sep 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 14:00:23
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:06:03
User entered '8 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 18:00:59

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 17:29:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:15
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:27:06
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 16:36:28
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	08 Jan 2021 18:26:29
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	08 Jan 2021 18:26:25
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	08 Jan 2021 18:26:25
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 15:30:43

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 17:29:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:04:09
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:54:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:54:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:06:03
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 18:00:59

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 17:29:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:15
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:06:03
User entered '1'	System	01 Oct 2020 18:00:59

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:15
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:06:03
User entered '1'	System	01 Oct 2020 18:00:59

FDA-CBER-2022-1614-1770715

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:15
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:06:03
User entered '804 (804)'	System	01 Oct 2020 18:00:59

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 17:29:09
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:32
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: KEFLEX [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 16:11:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 16:11:36
Data point term sent to Coder	System	02 Nov 2020 13:07:33
User entered 'KEFLEX'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:07:21

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 17:29:09
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:32
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:07:21

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 17:29:09
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:32
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'URINARY TRACT INFECTION'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:07:21

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 17:29:09
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:32
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '500'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:07:21

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 17:29:09
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:32
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:07:21

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 17:29:09
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:32
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:07:21

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 17:29:09
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:32
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:07:21

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 17:29:09
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:32
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:07:21

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 17:29:09
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:32
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:07:21

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 17:29:09
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:32
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:07:21

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 17:29:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:32
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '26 Aug 2020'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:07:21

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 17:29:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:32
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:07:21

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 17:29:09
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:32
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:07:21

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 17:29:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:32
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:41
DataPoint Un-verified.	Traci Hull (b) (4) (b) (4)	11 Nov 2020 14:00:36
User entered '06 Sep 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 14:00:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '6 Sep 2020'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:07:21

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 17:29:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:32
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:07:21

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 17:29:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:32
User entered '1'	System	02 Nov 2020 13:07:21

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:32
User entered '1'	System	02 Nov 2020 13:07:21

US3402382
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 17:29:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:32:32
User entered '804 (804)'	System	02 Nov 2020 13:07:21

US3402382
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 09 Jun 2021 17:29:09
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:52
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:22:59
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	30 Nov 2020 21:01:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	30 Nov 2020 21:01:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:04:34
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:47

US3402382
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 17:29:09
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:22:47
User entered '28 Aug 2020'	Tammy Kohn (b) (4) (b) (4)	30 Nov 2020 21:05:41

US3402382
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 17:29:09
Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:22:47
User entered 'COMPUTED TOMOGRAPHY HEAD/BRAIN W/O CONTRAST'	Tammy Kohn (b) (4) (b) (4)	30 Nov 2020 21:05:41

US3402382
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 17:29:09
Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 01:31:14
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 17:30:47
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 16:01:20
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:22:47
User entered 'Adverse Event (AE)'	Tammy Kohn (b) (4) (b) (4)	30 Nov 2020 21:05:41

US3402382
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 17:29:09
If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:22:47
User entered empty.	Tammy Kohn (b) (4) (b) (4)	30 Nov 2020 21:05:41

US3402382
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 09 Jun 2021 17:29:09
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:22:47
User entered '28 Aug 2020'	Tammy Kohn (b) (4) (b) (4)	30 Nov 2020 21:06:52

US3402382
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 09 Jun 2021 17:29:09
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:22:47
User entered 'CHEST XRAY'	Tammy Kohn (b) (4) (b) (4)	30 Nov 2020 21:06:52

US3402382
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 09 Jun 2021 17:29:09
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:22:47
User entered 'Adverse Event (AE)'	Tammy Kohn (b) (4) (b) (4)	30 Nov 2020 21:06:52

US3402382
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 09 Jun 2021 17:29:09
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:41:51
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:22:47
User entered empty.	Tammy Kohn (b) (4) (b) (4)	30 Nov 2020 21:06:52

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'USA-US059-2020-MRNA-1273-P301000002'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:33:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:29:32
User entered 'US' (non-conformant).	System	02 Sep 2020 13:12:53

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '8'	System	09 Mar 2021 15:33:27
User entered '7'	System	08 Mar 2021 16:57:29
User entered '6'	System	09 Nov 2020 16:14:45
User entered '5'	System	02 Nov 2020 14:29:35
User entered '4'	System	30 Oct 2020 14:04:04
User entered '3'	System	30 Sep 2020 17:21:46
User entered '2'	System	14 Sep 2020 20:29:42
User entered '1'	System	02 Sep 2020 13:12:53

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'USA-US059-2020-MRNA-1273-P301000002'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:33:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:29:32
User entered 'US' (non-conformant).	System	02 Sep 2020 13:12:53

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '8'	System	09 Mar 2021 15:33:27
User entered '7'	System	08 Mar 2021 16:57:29
User entered '6'	System	09 Nov 2020 16:14:45
User entered '5'	System	02 Nov 2020 14:29:35
User entered '4'	System	30 Oct 2020 14:04:04
User entered '3'	System	30 Sep 2020 17:21:46
User entered '2'	System	14 Sep 2020 20:29:42
User entered '1'	System	02 Sep 2020 13:12:53

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form (1)
Generated On: 09 Jun 2021 17:29:09
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
User entered '02/Sep/2020 09:12'	System	02 Sep 2020 13:12:53

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:29:09

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)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:29:32
User entered '1'	(b) (4), (b) (6)	02 Sep 2020 13:12:53

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'USA-US059-2020-MRNA-1273-P301000002'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

FDA-CBER-2022-1614-1770786

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:33:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:29:32
User entered 'US' (non-conformant).	System	02 Sep 2020 13:12:53

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '8'	System	09 Mar 2021 15:33:27
User entered '7'	System	08 Mar 2021 16:57:29
User entered '6'	System	09 Nov 2020 16:14:45
User entered '5'	System	02 Nov 2020 14:29:35
User entered '4'	System	30 Oct 2020 14:04:04
User entered '3'	System	30 Sep 2020 17:21:46
User entered '2'	System	14 Sep 2020 20:29:42
User entered '1'	System	02 Sep 2020 13:12:53

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 17:29:09
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
User entered '14/Sep/2020 16:29'	System	14 Sep 2020 20:29:42

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:29:09

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)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
User entered '1'	(b) (4), (b) (6)	14 Sep 2020 20:29:42

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'USA-US059-2020-MRNA-1273-P301000002'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

FDA-CBER-2022-1614-1770804

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

FDA-CBER-2022-1614-1770805

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:33:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:29:32
User entered 'US' (non-conformant).	System	02 Sep 2020 13:12:53

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '8'	System	09 Mar 2021 15:33:27
User entered '7'	System	08 Mar 2021 16:57:29
User entered '6'	System	09 Nov 2020 16:14:45
User entered '5'	System	02 Nov 2020 14:29:35
User entered '4'	System	30 Oct 2020 14:04:04
User entered '3'	System	30 Sep 2020 17:21:46
User entered '2'	System	14 Sep 2020 20:29:42
User entered '1'	System	02 Sep 2020 13:12:53

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form (3)
Generated On: 09 Jun 2021 17:29:09
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
User entered '30/Sep/2020 17:21'	System	30 Sep 2020 17:21:46

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:29:09

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)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 14:03:54
User entered '1'	(b) (4), (b) (6)	30 Sep 2020 17:21:46

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'USA-US059-2020-MRNA-1273-P301000002'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

FDA-CBER-2022-1614-1770822

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

FDA-CBER-2022-1614-1770823

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

FDA-CBER-2022-1614-1770825

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:33:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:29:32
User entered 'US' (non-conformant).	System	02 Sep 2020 13:12:53

FDA-CBER-2022-1614-1770828

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '8'	System	09 Mar 2021 15:33:27
User entered '7'	System	08 Mar 2021 16:57:29
User entered '6'	System	09 Nov 2020 16:14:45
User entered '5'	System	02 Nov 2020 14:29:35
User entered '4'	System	30 Oct 2020 14:04:04
User entered '3'	System	30 Sep 2020 17:21:46
User entered '2'	System	14 Sep 2020 20:29:42
User entered '1'	System	02 Sep 2020 13:12:53

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form (4)
Generated On: 09 Jun 2021 17:29:09
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
User entered '30/Oct/2020 14:04'	System	30 Oct 2020 14:04:04

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:29:09

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)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:29:23
User entered '1'	(b) (4), (b) (6)	30 Oct 2020 14:04:04

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'USA-US059-2020-MRNA-1273-P301000002'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

FDA-CBER-2022-1614-1770845

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:33:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:29:32
User entered 'US' (non-conformant).	System	02 Sep 2020 13:12:53

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '8'	System	09 Mar 2021 15:33:27
User entered '7'	System	08 Mar 2021 16:57:29
User entered '6'	System	09 Nov 2020 16:14:45
User entered '5'	System	02 Nov 2020 14:29:35
User entered '4'	System	30 Oct 2020 14:04:04
User entered '3'	System	30 Sep 2020 17:21:46
User entered '2'	System	14 Sep 2020 20:29:42
User entered '1'	System	02 Sep 2020 13:12:53

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form (5)
Generated On: 09 Jun 2021 17:29:09
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
User entered '02/Nov/2020 14:29'	System	02 Nov 2020 14:29:35

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:29:09

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)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:31:22
User entered '1'	(b) (4), (b) (6)	02 Nov 2020 14:29:35

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'USA-US059-2020-MRNA-1273-P301000002'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

FDA-CBER-2022-1614-1770858

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:33:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:29:32
User entered 'US' (non-conformant).	System	02 Sep 2020 13:12:53

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '8'	System	09 Mar 2021 15:33:27
User entered '7'	System	08 Mar 2021 16:57:29
User entered '6'	System	09 Nov 2020 16:14:45
User entered '5'	System	02 Nov 2020 14:29:35
User entered '4'	System	30 Oct 2020 14:04:04
User entered '3'	System	30 Sep 2020 17:21:46
User entered '2'	System	14 Sep 2020 20:29:42
User entered '1'	System	02 Sep 2020 13:12:53

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form (6)
Generated On: 09 Jun 2021 17:29:09
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:02:07
User entered '09/Nov/2020 11:14'	System	09 Nov 2020 16:14:45

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:29:09

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)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:33:05
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:02:08
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 16:14:45

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'USA-US059-2020-MRNA-1273-P301000002'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:33:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:29:32
User entered 'US' (non-conformant).	System	02 Sep 2020 13:12:53

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '8'	System	09 Mar 2021 15:33:27
User entered '7'	System	08 Mar 2021 16:57:29
User entered '6'	System	09 Nov 2020 16:14:45
User entered '5'	System	02 Nov 2020 14:29:35
User entered '4'	System	30 Oct 2020 14:04:04
User entered '3'	System	30 Sep 2020 17:21:46
User entered '2'	System	14 Sep 2020 20:29:42
User entered '1'	System	02 Sep 2020 13:12:53

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form (7)
Generated On: 09 Jun 2021 17:29:09
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:56:15
User entered '08/Mar/2021 11:57'	System	08 Mar 2021 16:57:29

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:29:09

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)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:56:17
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:33:05
User entered '1'	(b) (4), (b) (6)	08 Mar 2021 16:57:29

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'USA-US059-2020-MRNA-1273-P301000002'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

FDA-CBER-2022-1614-1770894

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

FDA-CBER-2022-1614-1770898

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

FDA-CBER-2022-1614-1770899

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:33:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:29:32
User entered 'US' (non-conformant).	System	02 Sep 2020 13:12:53

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:29:09
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '8'	System	09 Mar 2021 15:33:27
User entered '7'	System	08 Mar 2021 16:57:29
User entered '6'	System	09 Nov 2020 16:14:45
User entered '5'	System	02 Nov 2020 14:29:35
User entered '4'	System	30 Oct 2020 14:04:04
User entered '3'	System	30 Sep 2020 17:21:46
User entered '2'	System	14 Sep 2020 20:29:42
User entered '1'	System	02 Sep 2020 13:12:53

US3402382
Folder: SAE USA-US059-2020-MRNA-1273-P301000002
Form: Safety Report Form (8)
Generated On: 09 Jun 2021 17:29:09
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:56:04
User entered '09/Mar/2021 10:33'	System	09 Mar 2021 15:33:27

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:29:09

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)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:06
User entered '1'	(b) (4), (b) (6)	09 Mar 2021 15:33:27