US3312095 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:57:13

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US3312095
Form: Participant Creation
Data signed: (b) (4) **05 Apr 2021 17:44:26**
Generated On: 09 Jun 2021 16:57:13

Participant ID	US3312095

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-0869029

US3312095
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-0869030

US3312095
Folder: Screening
Form: Demographics
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

Date of Birth (MMM yyyy)	(b) (6) 1997
Age	23
Age Units	YEARS
Age (Derived)	23
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-2022-1614-0869031

US3312095
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

Date of Informed Consent *(dd MMM yyyy)*	17 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-2022-1614-0869032

US3312095
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

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

FDA-CBER-2022-1614-0869033

US3312095
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-0869034

US3312095
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

Condition	EXERCISE INDUCED ASTHMA
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes No
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

FDA-CBER-2022-1614-0869035

US3312095
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0869036

US3312095
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	17 AUG 2020
Time of assessment *(00:00-23:59)*	09:22 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 09:22
Height *(xxx.x)*	67 in
Weight *(xxx.x)*	184 lb
BMI *(xxx.x)*	28.87873 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0869037

US3312095
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	17 AUG 2020

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

FDA-CBER-2022-1614-0869038

US3312095
Folder: Screening
Form: Childbearing Potential
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

Date of assessment *(dd MMM yyyy)*	17 AUG 2020
Is the participant of childbearing potential?	Yes ■ No ☐
If No, what is the reason?	Surgically sterile ☐ Post-menopausal ☐ Partner medically sterile ☐ Not reached age of Menarche ☐ Other ☐
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	False

FDA-CBER-2022-1614-0869039

US3312095
Folder: Screening
Form: Pregnancy Test
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

Was the pregnancy test performed?	Yes ■ No ☐
Date of test *(dd MMM yyyy)*	17 AUG 2020
Test performed	Urine ■ Serum ☐
Result	Positive ☐ Negative ■
Was FSH sample collected?	Yes ☐ No ■
Collection date	
Collection time	
Collection date and time (derived)	

FDA-CBER-2022-1614-0869040

US3312095
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **15 Feb 2021 21:48:14**
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Occupational Risk	
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ■ No ☐
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐ No ■
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐ No ■
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐ No ■
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐ No ■
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐ No ■
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐ No ■
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐ No ■
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐ No ■
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐ No ■
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐ No ■
Other	Yes ☐ No ■
Specify	

Location and Living Circumstances Risk (check all that apply)	
No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False

FDA-CBER-2022-1614-0869041

US3312095
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **15 Feb 2021 21:48:14**
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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)	False
Other	True
Specify	RESIDES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

US3312095
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 21:48:16**
Generated On: 09 Jun 2021 16:57:13

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-0869043

US3312095
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **15 Feb 2021 21:48:16**
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What was the date of randomization? *(dd MMM yyyy)*	17 AUG 2020
What was the participant's randomization number?	104589
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-2022-1614-0869044

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **15 Feb 2021 21:48:16**
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Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-0869045

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **15 Feb 2021 21:48:16**
Generated On: 09 Jun 2021 16:57:13

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)*	17 AUG 2020
Time of assessment *(00:00-23:59)*	09:22 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 09:22
Temperature *(xxx.x)*	98.0 F
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)*	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	58 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0869046

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **15 Feb 2021 21:48:16**
Generated On: 09 Jun 2021 16:57:13

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)*	17 AUG 2020
Time of assessment *(00:00-23:59)*	11:04 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 11:04
Temperature *(xxx.x)*	97.6 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	55 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	71 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0869047

US3312095
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 21:48:16**
Generated On: 09 Jun 2021 16:57:13

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-2022-1614-0869048

US3312095
Folder: Visit 1 Day 1
Form: Pregnancy Test
Data signed: (b) (4) **15 Feb 2021 21:48:16**
Generated On: 09 Jun 2021 16:57:13

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

FDA-CBER-2022-1614-0869049

US3312095
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **15 Feb 2021 21:48:14**
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Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	17 AUG 2020
What was the treatment time? *(00:00-23:59)*	10:33 (24 HR)
Treatment Date and Time (derived)	17 AUG 2020 10:33
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-2022-1614-0869050

US3312095
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 21:48:16**
Generated On: 09 Jun 2021 16:57:13

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	17 AUG 2020
Collection time *(00:00-23:59)*	09:53 (24 HR)
Collection date and time (derived)	17 AUG 2020 09:53

FDA-CBER-2022-1614-0869051

US3312095
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

Collection date *(dd MMM yyyy)*			17 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:46	17 AUG 2020 09:46
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0869052

US3312095
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

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

FDA-CBER-2022-1614-0869053

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	17 AUG 2020 11:06
PC Open Date & Time	17 AUG 2020 10:53
PC Close Date & Time	17 AUG 2020 13:23

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	17 AUG 2020 21:05
PC Open Date & Time	17 AUG 2020 14:18
PC Close Date & Time	18 AUG 2020 11:59

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:57:13

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**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 AUG 2020 22:22
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	19 AUG 2020 22:54
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	20 AUG 2020 18:46
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	22 AUG 2020 00:43
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	23 AUG 2020 08:14
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:57:13

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**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	23 AUG 2020 23:41
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:57:13

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	17 AUG 2020 11:07
PC Open Date & Time	17 AUG 2020 10:53
PC Close Date & Time	17 AUG 2020 13:23

FDA-CBER-2022-1614-0869062

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:57:13

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	17 AUG 2020 21:05
PC Open Date & Time	17 AUG 2020 14:18
PC Close Date & Time	18 AUG 2020 11:59

FDA-CBER-2022-1614-0869063

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	18 AUG 2020 19:56
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

FDA-CBER-2022-1614-0869064

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:57:13

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	19 AUG 2020 22:56
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:57:13

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	20 AUG 2020 18:47
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	22 AUG 2020 00:43
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:57:13

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	23 AUG 2020 08:14
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

FDA-CBER-2022-1614-0869068

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:57:13

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 23:41
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-0869069

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 ☐

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	17 AUG 2020 11:07
PC Open Date & Time	17 AUG 2020 10:53
PC Close Date & Time	17 AUG 2020 13:23

FDA-CBER-2022-1614-0869071

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 ☐

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	17 AUG 2020 21:05
PC Open Date & Time	17 AUG 2020 14:18
PC Close Date & Time	18 AUG 2020 11:59

FDA-CBER-2022-1614-0869073

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13

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-2022-1614-0869074

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13

	Yes
PC Time stamp	18 AUG 2020 19:57
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

FDA-CBER-2022-1614-0869075

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13

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-2022-1614-0869076

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13

	Yes
PC Time stamp	19 AUG 2020 22:56
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

FDA-CBER-2022-1614-0869077

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 ■

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13

	Yes
PC Time stamp	20 AUG 2020 18:47
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

FDA-CBER-2022-1614-0869079

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13

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-2022-1614-0869080

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13

	Yes ☐
PC Time stamp	22 AUG 2020 00:44
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

FDA-CBER-2022-1614-0869081

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 ■

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13

	Yes ☐
PC Time stamp	23 AUG 2020 08:14
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

FDA-CBER-2022-1614-0869083

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 ■

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13

	Yes ☐
PC Time stamp	23 AUG 2020 23:42
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-0869085

US3312095
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

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-2022-1614-0869086

US3312095
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

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

FDA-CBER-2022-1614-0869087

US3312095
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	31 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-2022-1614-0869088

US3312095
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

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

FDA-CBER-2022-1614-0869089

US3312095
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	7 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-2022-1614-0869090

US3312095
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

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

FDA-CBER-2022-1614-0869091

US3312095
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 21:48:16**
Generated On: 09 Jun 2021 16:57:13

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-0869092

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **15 Feb 2021 21:48:16**
Generated On: 09 Jun 2021 16:57:13

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	21 SEP 2020
Time of assessment *(00:00-23:59)*	08:16 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 08:16
Temperature *(xxx.x)*	97.9 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	70 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	79 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0869093

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **15 Feb 2021 21:48:16**
Generated On: 09 Jun 2021 16:57:13

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	21 SEP 2020
Time of assessment *(00:00-23:59)*	09:56 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 09:56
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	63 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	82 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0869094

US3312095
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 21:48:16**
Generated On: 09 Jun 2021 16:57:13

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

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

FDA-CBER-2022-1614-0869095

US3312095
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Data signed: (b) (4) **15 Feb 2021 21:48:16**
Generated On: 09 Jun 2021 16:57:13

Was the pregnancy test performed?	Yes ■ No ☐
Date of test *(dd MMM yyyy)*	21 SEP 2020
Test performed	Urine ■ Serum ☐
Result	Positive ☐ Negative ■
Was FSH sample collected?	Yes ☐ No ■
Collection date	
Collection time	
Collection date and time (derived)	

FDA-CBER-2022-1614-0869096

US3312095
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **15 Feb 2021 21:48:16**
Generated On: 09 Jun 2021 16:57:13

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)*	21 SEP 2020
What was the treatment time? *(00:00-23:59)*	09:25 (24 HR)
Treatment Date and Time (derived)	21 SEP 2020 09:25
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-2022-1614-0869097

US3312095
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 21:48:16**
Generated On: 09 Jun 2021 16:57:13

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	21 SEP 2020
Collection time *(00:00-23:59)*	08:47 (24 HR)
Collection date and time (derived)	21 SEP 2020 08:47

FDA-CBER-2022-1614-0869098

US3312095
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **15 Feb 2021 21:48:16**
Generated On: 09 Jun 2021 16:57:13

Collection date *(dd MMM yyyy)*			21 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:41	21 SEP 2020 08:41
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0869099

US3312095
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 21:48:16**
Generated On: 09 Jun 2021 16:57:13

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

FDA-CBER-2022-1614-0869100

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	21 SEP 2020 10:00
PC Open Date & Time	21 SEP 2020 09:45
PC Close Date & Time	21 SEP 2020 12:15

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	21 SEP 2020 21:37
PC Open Date & Time	21 SEP 2020 13:10
PC Close Date & Time	22 SEP 2020 11:59

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:57:13

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**	98.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	22 SEP 2020 15:44
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:57:13

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**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	23 SEP 2020 23:59
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:57:13

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**	98.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	25 SEP 2020 06:58
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	25 SEP 2020 23:59
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:57:13

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**	98.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	27 SEP 2020 09:41
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	27 SEP 2020 23:59
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:57:13

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	21 SEP 2020 10:00
PC Open Date & Time	21 SEP 2020 09:45
PC Close Date & Time	21 SEP 2020 12:15

FDA-CBER-2022-1614-0869109

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:57:13

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	21 SEP 2020 21:37
PC Open Date & Time	21 SEP 2020 13:10
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-0869110

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	22 SEP 2020 15:44
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:57:13

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

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:57:13

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	25 SEP 2020 06:58
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	25 SEP 2020 23:59
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:57:13

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	27 SEP 2020 09:41
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

FDA-CBER-2022-1614-0869115

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:57:13

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	27 SEP 2020 23:59
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

FDA-CBER-2022-1614-0869116

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 ☐

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	21 SEP 2020 10:00
PC Open Date & Time	21 SEP 2020 09:45
PC Close Date & Time	21 SEP 2020 12:15

FDA-CBER-2022-1614-0869118

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13

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-2022-1614-0869119

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ■
PC Time stamp	21 SEP 2020 21:37
PC Open Date & Time	21 SEP 2020 13:10
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-0869120

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13

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-2022-1614-0869121

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13

	Yes ☐
PC Time stamp	22 SEP 2020 15:44
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13

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-2022-1614-0869123

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13

	Yes ☐
PC Time stamp	23 SEP 2020 23:59
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

FDA-CBER-2022-1614-0869124

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13

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-2022-1614-0869125

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13

	Yes
PC Time stamp	25 SEP 2020 06:58
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 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 ■

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13

	Yes ☐
PC Time stamp	25 SEP 2020 23:59
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

FDA-CBER-2022-1614-0869128

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13

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-2022-1614-0869129

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13

	Yes ☐
PC Time stamp	27 SEP 2020 09:41
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

FDA-CBER-2022-1614-0869130

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 ■

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13

	Yes ☐
PC Time stamp	27 SEP 2020 23:59
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

FDA-CBER-2022-1614-0869132

US3312095
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

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-2022-1614-0869133

US3312095
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

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

FDA-CBER-2022-1614-0869134

US3312095
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

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-2022-1614-0869135

US3312095
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

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

FDA-CBER-2022-1614-0869136

US3312095
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	12 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0869137

US3312095
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 21:48:14**
Generated On: 09 Jun 2021 16:57:13

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

FDA-CBER-2022-1614-0869138

US3312095
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 21:48:16**
Generated On: 09 Jun 2021 16:57:13

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	21 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-0869139

US3312095
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **15 Feb 2021 21:48:16**
Generated On: 09 Jun 2021 16:57:13

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	21 OCT 2020
Time of assessment *(00:00-23:59)*	13:02 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 13:02
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	66 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312095
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 21:48:16**
Generated On: 09 Jun 2021 16:57:13

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-2022-1614-0869141

US3312095
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 21:48:16**
Generated On: 09 Jun 2021 16:57:13

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	21 OCT 2020
Collection time *(00:00-23:59)*	13:16 (24 HR)
Collection date and time (derived)	21 OCT 2020 13:16

FDA-CBER-2022-1614-0869142

US3312095
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 21:48:16**
Generated On: 09 Jun 2021 16:57:13

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

FDA-CBER-2022-1614-0869143

US3312095
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 OCT 2020 00:01:55
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

FDA-CBER-2022-1614-0869144

US3312095
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

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	24 OCT 2020 05:55:32
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

FDA-CBER-2022-1614-0869145

US3312095
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 OCT 2020 00:01:23
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

FDA-CBER-2022-1614-0869146

US3312095
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 ☐
Date and time of submission	14 NOV 2020 00:01:55
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

FDA-CBER-2022-1614-0869147

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

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	21 NOV 2020 06:40:43
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

FDA-CBER-2022-1614-0869148

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 ☐
Date and time of submission	25 NOV 2020 01:44:25
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

FDA-CBER-2022-1614-0869149

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

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	02 DEC 2020 00:28:38
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

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	09 DEC 2020 08:24:16
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 01:04:47
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

FDA-CBER-2022-1614-0869152

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

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	23 DEC 2020 00:02:56
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

FDA-CBER-2022-1614-0869153

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

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	30 DEC 2020 04:58:01
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

FDA-CBER-2022-1614-0869154

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 JAN 2021 09:18:28
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

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	13 JAN 2021 09:09:54
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

FDA-CBER-2022-1614-0869156

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

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	20 JAN 2021 03:58:41
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

FDA-CBER-2022-1614-0869157

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

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	28 JAN 2021 12:46:18
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

FDA-CBER-2022-1614-0869158

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

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	03 FEB 2021 00:02:14
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

FDA-CBER-2022-1614-0869159

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

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 00:42:58
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

FDA-CBER-2022-1614-0869160

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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	17 FEB 2021 18:16:56
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

FDA-CBER-2022-1614-0869161

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

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	24 FEB 2021 01:00:29
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

FDA-CBER-2022-1614-0869162

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

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	04 MAR 2021 09:20:09
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

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	10 MAR 2021 06:40:02
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

FDA-CBER-2022-1614-0869164

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13

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	18 MAR 2021 18:14:30
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

FDA-CBER-2022-1614-0869165

US3312095
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 09 Jun 2021 16:57:13

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 19:27:45

FDA-CBER-2022-1614-0869166

US3312095
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **05 Apr 2021 17:44:28**
Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	16 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-2022-1614-0869167

US3312095
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **05 Apr 2021 17:44:28**
Generated On: 09 Jun 2021 16:57:13

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

FDA-CBER-2022-1614-0869168

US3312095
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **05 Apr 2021 17:44:28**
Generated On: 09 Jun 2021 16:57:13

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*	OCCURRED DURING CONVALESCENT PERIOD

FDA-CBER-2022-1614-0869169

US3312095
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **05 Apr 2021 17:44:28**
Generated On: 09 Jun 2021 16:57:13

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

FDA-CBER-2022-1614-0869170

US3312095
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **05 Apr 2021 17:44:28**
Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	19 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-2022-1614-0869171

US3312095
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **05 Apr 2021 17:44:28**
Generated On: 09 Jun 2021 16:57:13

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

FDA-CBER-2022-1614-0869172

US3312095
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **05 Apr 2021 17:44:28**
Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 FEB 2021
Please select one status for the follow-up contact	Contact Made ☐ Contact Not Made ■
Comments *If Contact Not Made, please provide Comments*	ATTEMPTS MADE ON 15FEB21, 16FEB21, AND 17FEB21. DEVIATION NOTED.

US3312095
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **05 Apr 2021 17:44:28**
Generated On: 09 Jun 2021 16:57:13

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

FDA-CBER-2022-1614-0869174

US3312095
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13

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

FDA-CBER-2022-1614-0869175

US3312095
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13

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-2022-1614-0869176

US3312095
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:57:13

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

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

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: COVID-19 Contact
Data signed: (b) (4) **05 Apr 2021 17:44:27**
Generated On: 09 Jun 2021 16:57:13

Date of Contact	04 DEC 2020
Time of Contact	16:56
Date and Time of Contact (derived)	04 DEC 2020 16:56
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-2022-1614-0869180

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

Symptom Day

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

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	03 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

	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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

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

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	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	04 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

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

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US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

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 ☐

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	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	05 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

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

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

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

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

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	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	06 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

	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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

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-2022-1614-0869197

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	07 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	98.6 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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

	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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

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 ☐

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	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	08 DEC 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	98.8 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

	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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

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 ☐

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	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	09 DEC 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.6 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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

	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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

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-2022-1614-0869209

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	10 DEC 2020
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	97.8 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

	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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

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-2022-1614-0869213

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	11 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	98.7 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

	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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

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

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	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	12 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.5 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

	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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

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-2022-1614-0869221

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	13 DEC 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	98.7 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

	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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

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

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	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	14 DEC 2020
Assessment Not Done	False
O2 Saturation	95 %
O2 Saturation Units	%
Temperature	98.8 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

	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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

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

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	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	15 DEC 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	98.5 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

	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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

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

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	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	16 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	98.5 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

	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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

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

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	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	17 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	98.6 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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

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

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	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	18 DEC 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.7 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

	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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

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

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	19 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Data signed: (b) (4) **05 Apr 2021 18:26:44**
Generated On: 09 Jun 2021 16:57:13

	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 ☐

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: COVID Diagnostic Test
Data signed: (b) (4) **28 Apr 2021 21:58:41**
Generated On: 09 Jun 2021 16:57:13

Date of Visit	10 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ■ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ■ No ☐
Date of Test	10 DEC 2020
Type of Test Performed	Nasopharyngeal Swab ☐ Nasal Swab ☐ Saliva Test ■ Other ☐
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ■
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	1

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Data signed: (b) (4) **05 Apr 2021 17:44:27**
Generated On: 09 Jun 2021 16:57:13

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

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

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

Hepatic Dysfunction?	Yes ☐ No ■
Start Date	
Neurologic Dysfunction?	Yes ☐ No ■
Start Date	
Evidence of Pneumonia:	
Clinical Evidence	Yes ☐ No ■
Date of Assessment	
Radiographical Evidence	Yes ☐ No ■
Date of Assessment	

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

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Generate Next COVID-19 Assessment
Data signed: (b) (4) **05 Apr 2021 17:44:27**
Generated On: 09 Jun 2021 16:57:13

Generate Next COVID-19 Assessment	Yes ☐ No ■

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US3312095
Folder: Illness Visit (1)
Form: Saliva Collection
Data signed: (b) (4) **05 Apr 2021 17:44:27**
Generated On: 09 Jun 2021 16:57:13

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	Yes	10 DEC 2020
Day 7	Yes	12 DEC 2020
Day 9	Yes	14 DEC 2020
Day 14	Yes	19 DEC 2020
Day 21	Yes	26 DEC 2020
Day 28	Yes	04 JAN 2021

US3312095
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Data signed: (b) (4) **05 Apr 2021 17:44:27**
Generated On: 09 Jun 2021 16:57:13

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

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US3312095
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Data signed: (b) (4) **05 Apr 2021 17:44:27**
Generated On: 09 Jun 2021 16:57:13

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)	

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US3312095
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Data signed: (b) (4) **05 Apr 2021 17:44:27**
Generated On: 09 Jun 2021 16:57:13

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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US3312095
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **05 Apr 2021 17:44:27**
Generated On: 09 Jun 2021 16:57:13

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

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US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Data signed: (b) (4) **05 Apr 2021 17:44:27**
Generated On: 09 Jun 2021 16:57:13

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	04 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SICKD28

FDA-CBER-2022-1614-0869259

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Data signed: (b) (4) **05 Apr 2021 17:44:27**
Generated On: 09 Jun 2021 16:57:13

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	04 JAN 2021
Time of assessment *(00:00-23:59)*	10:13 (24 HR)
Vital Signs Date and Time (derived)	04 JAN 2021 10:13
Height *(xxx.x)*	ND - Not Done
Weight *(xxx.x)*	ND - Not Done
Temperature *(xxx.x)*	97.7 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	63 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0869260

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Data signed: (b) (4) **05 Apr 2021 17:44:27**
Generated On: 09 Jun 2021 16:57:13

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	04 JAN 2021

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

FDA-CBER-2022-1614-0869261

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **05 Apr 2021 17:44:27**
Generated On: 09 Jun 2021 16:57:13

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ■ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	04 JAN 2021

FDA-CBER-2022-1614-0869262

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **05 Apr 2021 17:44:27**
Generated On: 09 Jun 2021 16:57:13

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

FDA-CBER-2022-1614-0869263

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **15 Apr 2021 19:42:41**
Generated On: 09 Jun 2021 16:57:13

Date of updated informed consent *(dd MMM yyyy)*	
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)*	10 MAR 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	

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US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **05 Apr 2021 17:44:27**
Generated On: 09 Jun 2021 16:57:13

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

FDA-CBER-2022-1614-0869265

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **05 Apr 2021 17:44:27**
Generated On: 09 Jun 2021 16:57:13

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

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US3312095
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **12 Mar 2021 15:45:47**
Generated On: 09 Jun 2021 16:57:13

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

If Yes, enter details on the Adverse Events form.

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US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **08 Apr 2021 15:44:12**
Generated On: 09 Jun 2021 16:57:13

AEID	USA-US300-2020-MRNA-1273-P30 1000017
Adverse event	SYMPTOMATIC COVID-19
Was this a medically-attended AE?	Yes ■ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ■ No ☐
Start date *(dd MMM yyyy)*	03 DEC 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	12 DEC 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 ☐

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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	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

	01DEC SUBJ NOTED TEMP 99.8. AG TEST NEG. 03DEC MILDLY SHORT OF BREATH, MYALGIA, BLUNTED TASTE/SMELL, NO OTHER SYMPTOMS. AG TEST POS. NO ASSOCIATED CON MEDS. SUBJ (b) (6) (b) (6) NOW DUE TO NEW TRAVELING NURSE ASSIGNMENT, WITH UNKNOWN RETURN DATE. CAN'T DO ILLNESS VISIT. WILL COORDINATE CONVALESCENT PHONE VISITS AND TESTING.
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)	

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **08 Apr 2021 15:44:12**
Generated On: 09 Jun 2021 16:57:13

AEID	USA-US300-2021-MRNA-1273-P30 1000019
Adverse event	PNEUMONIA
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)*	12 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	24 FEB 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ■ Grade 4 ☐
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	19 FEB 2021
Hospital Discharge Date *(dd MMM yyyy)*	22 FEB 2021
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:	RESIDUAL EXERCISE INTOLERANCE AND NECK STIFFNESS

Narrative

23 Y/O FEMALE TRAVELLING NURSE WITH H/O ASTHMA, SEASONAL ALLERGIES, AND SYMPTOMATIC COVID IN EARLY DEC2020 DEVELOPED SORE THROAT WITH ENLARGED ANTERIOR CERVICAL LYMPH NODE AND HEADACHE ON 15FEB21 THAT INCREASED IN SEVERITY PROMPTING ER VISIT; CT HEAD AND NECK ON SAME DAY WERE NEGATIVE AND SUBJECT WAS D/C'D TO HOME. ON 17FEB20 SUBJECT DEVELOPED FEVER, SHORTNESS OF AIR AND CHEST PAIN FOR WHICH SHE RETURNED TO ER AND RECEIVED IV FLUIDS AND HAD NEGATIVE CXR, REPEAT CT HEAD, AND ECHOCARDIOGRAM AND WAS D/C'D TO HOME ON AUGMENTIN AND ZPAC. ON 19FEB20 SUBJECT CONTINUED TO BE ILL AND HER PCP DIRECTLY ADMITTED HER TO A DIFFERENT HOSPITAL WHERE PULMONARY SCANS RULED OUT PE'S BUT CXR REVEALED BILATERAL PNEUMONIA AND LP WAS CONSISTENT WITH ASEPTIC MENINGITIS. SHE WAS TREATED WITH STEROIDS,

	OXYGEN, STEROIDS, VANCOMYCIN, ZOSYN, AND LEVAQUIN AND D/C'D TO HOME ON 22FEB20 ON ORAL LEVAQUIN AND DEXAMETHASONE. TODAY SUBJECT HAS MILD HEADACHE, FATIGUE, AND SHORTNESS OF AIR. WILL PROCURE MEDICAL RECORDS. SUBJECT DID NOT REPORT SYMPTOMS IN EDIARY AND ILLNESS VISIT WILL NOT BE DONE DUE TO CURRENTLY BEING A TRAVEL NURSE AND LIVES OUT OF TOWN.3/10/21: MED RECORDS DC SUMMARY AND UPDATED NARRATIVE SUBMITTED VIA EMAIL DUE TO CHARACTER LENGTH NOT SUFFICIENT
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

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Data signed: (b) (4) **08 Apr 2021 15:44:12**
Generated On: 09 Jun 2021 16:57:13

AEID	USA-US300-2021-MRNA-1273-P30 1000019
Adverse event	ASEPTIC MENINGITIS
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)*	12 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	06 MAR 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ■ Grade 4 ☐
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	19 FEB 2021
Hospital Discharge Date *(dd MMM yyyy)*	22 FEB 2021
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:	ONGOING EXERCISE INTOLERANCE AND NECK STIFFNESS
Narrative	

23 Y/O FEMALE TRAVELLING NURSE WITH H/O ASTHMA, SEASONAL ALLERGIES, AND SYMPTOMATIC COVID IN EARLY DEC2020 DEVELOPED SORE THROAT WITH ENLARGED ANTERIOR CERVICAL LYMPH NODE AND HEADACHE ON 15FEB21 THAT INCREASED IN SEVERITY PROMPTING ER VISIT; CT HEAD AND NECK ON SAME DAY WERE NEGATIVE AND SUBJECT WAS D/C'D TO HOME. ON 17FEB20 SUBJECT DEVELOPED FEVER, SHORTNESS OF AIR AND CHEST PAIN FOR WHICH SHE RETURNED TO ER AND RECEIVED IV FLUIDS AND HAD NEGATIVE CXR, REPEAT CT HEAD, AND ECHOCARDIOGRAM AND WAS D/C'D TO HOME ON AUGMENTIN AND ZPAC. ON 19FEB20 SUBJECT CONTINUED TO BE ILL AND HER PCP DIRECTLY ADMITTED HER TO A DIFFERENT HOSPITAL WHERE PULMONARY SCANS RULED OUT PE'S BUT CXR REVEALED BILATERAL PNEUMONIA AND LP WAS CONSISTENT WITH ASEPTIC MENINGITIS. SHE WAS TREATED WITH STEROIDS,

	OXYGEN, STEROIDS, VANCOMYCIN, ZOSYN, AND LEVAQUIN AND D/C'D TO HOME ON 22FEB20 ON ORAL LEVAQUIN AND DEXAMETHASONE. TODAY SUBJECT HAS MILD HEADACHE, FATIGUE, AND SHORTNESS OF AIR. WILL PROCURE MEDICAL RECORDS. COVID TEST NEGATIVE IN HOSPITAL 19FEB2021. 10MAR2021 MEDRECORDS DC SUMMARY AND UPDATED NARRATIVE SUBMITTED VIA EMAIL DUE TO CHARACTER LENGTH NOT SUFFICIENT
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

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **05 Apr 2021 17:44:27**
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Were any prior/concomitant medications and/or vaccinations taken?	Yes ■ No ☐

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

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US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
Generated On: 09 Jun 2021 16:57:13

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

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

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
Generated On: 09 Jun 2021 16:57:13

Name of Medication	VITAMIN D
Prophylaxis	Yes ■ No ☐
Indication	HEALTH MAINTENANCE
Dose per administration	3000
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ■ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
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Name of Medication	MIRENA
Prophylaxis	Yes ■ No ☐
Indication	BIRTH CONTROL
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	INTRAUTERINE DEVICE
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	ONCE EVERY 5 YEARS
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	INTRAUTERINE
Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
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Name of Medication	INFLUENZA VACCINATION
Prophylaxis	Yes ■ No ☐
Indication	SEASONAL INFLUENZA PROPHYLAXIS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	INJECTION
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ■
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	05 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	05 SEP 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
Generated On: 09 Jun 2021 16:57:13

Name of Medication	AMOXICILLIN / CLAVULANIC
Prophylaxis	Yes ☐ No ■
Indication	PNEUMONIA
Dose per administration	875/125
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)*	12 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	19 FEB 2021
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
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Name of Medication	AZITHROMYCIN
Prophylaxis	Yes ☐ No ■
Indication	PNEUMONIA
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 ☐

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	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	17 FEB 2021
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 ☐

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
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Name of Medication	AZITHROMYCIN
Prophylaxis	Yes ○ No ●
Indication	PNEUMONIA
Dose per administration	250
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)*	18 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	19 FEB 2021
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 ■

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
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Name of Medication	VANCOMYCIN
Prophylaxis	Yes ☐ No ■
Indication	PNEUMONIA
Dose per administration	UNK
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)*	19 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	21 FEB 2021
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 ☐

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
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Name of Medication	PIPERACILLIN / TAZOBACTAM
Prophylaxis	Yes ○ No ●
Indication	PNEUMONIA
Dose per administration	3/0.375
Dose unit	mg ○ ug ○ mL ○ g ● IU ○ tablet ○ capsule ○ puff ○ Other ○
If dose unit is Other, specify	
Frequency	once daily ○ twice daily ○ three times daily ○ four times daily ● every other day ○ every week ○ every month ○ as needed ○ once ○ unknown ○ other ○
If frequency is Other, specify	
Route of administration	Oral ○ Topical ○ Subcutaneous ○ Transdermal ○ Intraocular ○

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	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	19 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	21 FEB 2021
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
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Name of Medication	NORMAL SALINE
Prophylaxis	Yes No ■
Indication	PNEUMONIA, ASEPTIC MENINGITIS
Dose per administration	1000
Dose unit	mg ug mL ■ g IU tablet capsule puff Other
If dose unit is Other, specify	
Frequency	once daily twice daily three times daily four times daily every other day every week every month as needed once ■ unknown other
If frequency is Other, specify	
Route of administration	Oral Topical Subcutaneous Transdermal

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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)*	19 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	19 FEB 2021
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 ☐

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
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Name of Medication	FENTANYL
Prophylaxis	Yes ☐ No ■
Indication	PNEUMONIA, ASEPTIC MENINGITIS
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 ☐

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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)*	19 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	19 FEB 2021
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 ☐

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
Generated On: 09 Jun 2021 16:57:13

Name of Medication	ONDANSETRON
Prophylaxis	Yes ☐ No ■
Indication	PNEUMONIA, ASEPTIC MENINGITIS
Dose per administration	8
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)*	19 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	19 FEB 2021
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 ☐

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
Generated On: 09 Jun 2021 16:57:13

Name of Medication	OXYGEN
Prophylaxis	Yes ☐ No ■
Indication	PNEUMONIA
Dose per administration	0-5
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	LITER
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)*	19 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	22 FEB 2021
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 ☐

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
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Name of Medication	OXYCODONE
Prophylaxis	Yes ☐ No ■
Indication	PNEUMONIA, ASEPTIC MENINGITIS
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 ☐

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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)*	19 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	23 FEB 2021
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 ☐

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
Generated On: 09 Jun 2021 16:57:13

Name of Medication	LEVAQUIN
Prophylaxis	Yes ☐ No ■
Indication	PNEUMONIA
Dose per administration	750
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)*	19 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	25 FEB 2021
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 ■

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
Generated On: 09 Jun 2021 16:57:13

Name of Medication	NORMAL SALINE
Prophylaxis	Yes ☐ No ■
Indication	PNEUMONIA, ASEPTIC MENINGITIS
Dose per administration	125
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	HOURLY
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)*	19 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	20 FEB 2021
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 ☐

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
Generated On: 09 Jun 2021 16:57:13

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

	Intraocular ☐
	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)*	12 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	06 MAR 2021
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 ☐

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
Generated On: 09 Jun 2021 16:57:13

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ■
Indication	ASEPTIC MENINGITIS
Dose per administration	600
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)*	12 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	19 FEB 2021
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 ☐

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
Generated On: 09 Jun 2021 16:57:13

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ■
Indication	ASEPTIC MENINGITIS
Dose per administration	600
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)*	22 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	06 MAR 2021
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 ☐

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
Generated On: 09 Jun 2021 16:57:13

Name of Medication	DOCUSATE
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 ☐

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	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	19 FEB 2021
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)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
Generated On: 09 Jun 2021 16:57:13

Name of Medication	PANTOPRAZOLE
Prophylaxis	Yes ■ No ☐
Indication	GASTRITIS PROPHYLAXIS
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 ☐

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	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	19 FEB 2021
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 ■

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
Generated On: 09 Jun 2021 16:57:13

Name of Medication	DEXAMETHASONE
Prophylaxis	Yes ☐ No ■
Indication	PNEUMONIA
Dose per administration	6
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)*	19 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	22 FEB 2021
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 ■

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
Generated On: 09 Jun 2021 16:57:13

Name of Medication	DEXAMETHASONE
Prophylaxis	Yes ☐ No ■
Indication	PNEUMONIA
Dose per administration	6
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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	Intramuscular ☐ Respiratory (Inhalation) ☐ Intralesional ☐ Intraperiteoneal ☐ Nasal ☐ Vaginal ☐ Rectal ☐ Intravenous ☐ Intravenous Bolus ☐ Intravenous Drip ☐ Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	23 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	28 FEB 2021
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 ■

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
Generated On: 09 Jun 2021 16:57:13

Name of Medication	MECLIZINE
Prophylaxis	Yes ☐ No ■
Indication	ASEPTIC MENINGITIS
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-2022-1614-0869326

	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)*	23 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	25 FEB 2021
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 ☐

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Data signed: (b) (4) **05 Apr 2021 20:50:59**
Generated On: 09 Jun 2021 16:57:13

Name of Medication	CYCLOBENZAPRINE
Prophylaxis	Yes No
Indication	ASEPTIC MENINGITIS
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

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	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	12 FEB 2021
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 ☐

US3312095
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **15 Apr 2021 19:42:41**
Generated On: 09 Jun 2021 16:57:13

Were any concomitant procedures performed?	Yes ☐ No ☒

If yes, please complete Concomitant Procedures form.

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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	_____

US3312095
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **22 Apr 2021 20:38:38**
Generated On: 09 Jun 2021 16:57:13

Date of study discontinuation/completion *(dd MMM yyyy)*	10 MAR 2021
Reason for discontinuation	AE (specify) ☐ SAE (specify) ☐ Complete ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Other ■
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	COVID 19 EUA VACCINE OUTSIDE OF STUDY
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 ☐

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Data signed: (b) (4) **05 Apr 2021 17:44:28**
Generated On: 09 Jun 2021 16:57:13

SAEID	USA-US300-2020-MRNA-1273-P301000017
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form (1)
Data signed: (b) (4) **05 Apr 2021 17:44:28**
Generated On: 09 Jun 2021 16:57:13

SAEID	USA-US300-2020-MRNA-1273-P301000017
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	08/DEC/2020 05:55
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

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form (2)
Data signed: (b) (4) **05 Apr 2021 17:44:28**
Generated On: 09 Jun 2021 16:57:13

SAEID	USA-US300-2020-MRNA-1273-P301000017
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/DEC/2020 15:07
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

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form (3)
Data signed: (b) (4) **05 Apr 2021 17:44:28**
Generated On: 09 Jun 2021 16:57:13

SAEID	USA-US300-2020-MRNA-1273-P301000017
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	30/DEC/2020 14:07
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

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form (4)
Data signed: (b) (4) **05 Apr 2021 17:44:28**
Generated On: 09 Jun 2021 16:57:13

SAEID	USA-US300-2020-MRNA-1273-P301000017
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	05/JAN/2021 14:33
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

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form (5)
Data signed: (b) (4) **05 Apr 2021 17:44:28**
Generated On: 09 Jun 2021 16:57:13

SAEID	USA-US300-2020-MRNA-1273-P301000017
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	26/FEB/2021 15:17
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

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Data signed: (b) (4) **05 Apr 2021 17:44:28**
Generated On: 09 Jun 2021 16:57:13

SAEID	USA-US300-2021-MRNA-1273-P301000019
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form (1)
Data signed: (b) (4) **05 Apr 2021 17:44:28**
Generated On: 09 Jun 2021 16:57:13

SAEID	USA-US300-2021-MRNA-1273-P301000019
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	24/FEB/2021 12:35
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

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form (2)
Data signed: (b) (4) **05 Apr 2021 17:44:28**
Generated On: 09 Jun 2021 16:57:13

SAEID	USA-US300-2021-MRNA-1273-P301000019
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	11/MAR/2021 09:51
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

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form (3)
Data signed: (b) (4) **05 Apr 2021 17:44:28**
Generated On: 09 Jun 2021 16:57:13

SAEID	USA-US300-2021-MRNA-1273-P301000019
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/MAR/2021 08:52
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

US3312095 (Prod: Johnson County Clin-Trials)

US3312095
Form: Participant Creation
Generated On: 09 Jun 2021 16:57:13
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:25:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'US3312095'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	17 Aug 2020 14:00:01

FDA-CBER-2022-1614-0869344

US3312095
Form: Participant Creation
Generated On: 09 Jun 2021 16:57:13

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57

FDA-CBER-2022-1614-0869345

US3312095
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:34:20
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:38:10

US3312095
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:34:20
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	17 Aug 2020 14:00:03

FDA-CBER-2022-1614-0869347

US3312095
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
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 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:34:20
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:38:10

FDA-CBER-2022-1614-0869348

US3312095
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'SCRN'	System	17 Aug 2020 15:38:10

FDA-CBER-2022-1614-0869349

US3312095
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:57:13
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:20
User entered (b) (6) 1997'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	17 Aug 2020 14:00:05

FDA-CBER-2022-1614-0869350

US3312095
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:57:13
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:20
User entered '23'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:40:11

FDA-CBER-2022-1614-0869351

US3312095
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:57:13
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'YEARS'	System	24 Aug 2020 21:40:11

FDA-CBER-2022-1614-0869352

US3312095
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:57:13
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered '23'	System	17 Aug 2020 15:38:26

FDA-CBER-2022-1614-0869353

US3312095
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:57:13
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:20
User entered 'Female (F)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:40:11

FDA-CBER-2022-1614-0869354

US3312095
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:57:13
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:20
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:40:11

FDA-CBER-2022-1614-0869355

US3312095
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:57:13
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:20
User entered '1'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:40:11

FDA-CBER-2022-1614-0869356

US3312095
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:57:13
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:20
User entered '0'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:40:11

FDA-CBER-2022-1614-0869357

US3312095
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:57:13
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:20
User entered '0'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:40:11

FDA-CBER-2022-1614-0869358

US3312095
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:57:13
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:20
User entered '0'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:40:11

FDA-CBER-2022-1614-0869359

US3312095
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:57:13
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:20
User entered '0'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:40:11

FDA-CBER-2022-1614-0869360

US3312095
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:57:13
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:20
User entered '0'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:40:11

FDA-CBER-2022-1614-0869361

US3312095
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:57:13
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:20
User entered empty.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:40:11

FDA-CBER-2022-1614-0869362

US3312095
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:57:13
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:20
User entered '0'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:40:11

FDA-CBER-2022-1614-0869363

US3312095
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:57:13
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:20
User entered '0'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:40:11

FDA-CBER-2022-1614-0869364

US3312095
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:57:13
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:11
User entered '17 Aug 2020'	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:38:26

FDA-CBER-2022-1614-0869365

US3312095
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:57:13
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'Aug 2020'	System	17 Aug 2020 15:38:26

FDA-CBER-2022-1614-0869366

US3312095
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:57:13
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered '2020'	System	17 Aug 2020 15:38:26

FDA-CBER-2022-1614-0869367

US3312095
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:57:13
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:11
User entered 'Amendment 2 (2)'	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:38:26

US3312095
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:57:13
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:11
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:38:26

FDA-CBER-2022-1614-0869369

US3312095
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:57:13
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:11
User entered empty.	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:38:26

US3312095
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:57:13
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:11
User entered empty.	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:38:26

US3312095
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:57:13
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:11
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:38:26

US3312095
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:57:13
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:11
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	17 Aug 2020 14:00:03

FDA-CBER-2022-1614-0869373

US3312095
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:57:13
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered '1'	System	17 Aug 2020 15:38:33

FDA-CBER-2022-1614-0869374

US3312095
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 09 Jun 2021 16:57:13
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:46:45
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:38:33

US3312095
Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 16:57:13
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:36
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:40:21

FDA-CBER-2022-1614-0869376

US3312095
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:57:13
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:46
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma exercise induced, LLT: Exercise induced asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 21:42:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 21:42:43
Data point term sent to Coder	System	24 Aug 2020 21:41:47
User entered 'exercise induced asthma'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:41:02

FDA-CBER-2022-1614-0869377

US3312095
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:57:13
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:46
User entered 'un UNK 2014'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:41:02

FDA-CBER-2022-1614-0869378

US3312095
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:46
User entered '0'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:41:02

FDA-CBER-2022-1614-0869379

US3312095
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:57:13
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:46
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:41:02

FDA-CBER-2022-1614-0869380

US3312095
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:57:13
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:46
User entered 'un UNK 2015'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:41:02

US3312095
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:57:13
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:46
User entered '0'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:41:02

FDA-CBER-2022-1614-0869382

US3312095
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:57:13
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'Jan 2014'	System	24 Aug 2020 21:41:02

FDA-CBER-2022-1614-0869383

US3312095
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:57:13
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered '2014'	System	24 Aug 2020 21:41:02

FDA-CBER-2022-1614-0869384

US3312095
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:57:13
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'Jan 2015'	System	24 Aug 2020 21:41:02

FDA-CBER-2022-1614-0869385

US3312095
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:57:13
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered '2015'	System	24 Aug 2020 21:41:02

FDA-CBER-2022-1614-0869386

US3312095
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:57:13
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:46
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 21:42:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 21:42:43
Data point term sent to Coder	System	24 Aug 2020 21:41:47
User entered 'seasonal allergies'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:41:24

FDA-CBER-2022-1614-0869387

US3312095
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:57:13
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:46
User entered 'un UNK 2007'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:41:24

FDA-CBER-2022-1614-0869388

US3312095
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:46
User entered '0'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:41:24

FDA-CBER-2022-1614-0869389

US3312095
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:57:13
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:46
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:41:24

FDA-CBER-2022-1614-0869390

US3312095
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:57:13
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:46
User entered empty.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:41:24

FDA-CBER-2022-1614-0869391

US3312095
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:57:13
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:40:46
User entered '0'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:41:24

US3312095
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:57:13
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'Jan 2007'	System	24 Aug 2020 21:41:24

FDA-CBER-2022-1614-0869393

US3312095
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:57:13
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered '2007'	System	24 Aug 2020 21:41:24

FDA-CBER-2022-1614-0869394

US3312095
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:57:13
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered empty.	System	24 Aug 2020 21:41:24

FDA-CBER-2022-1614-0869395

US3312095
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:57:13
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered empty.	System	24 Aug 2020 21:41:24

FDA-CBER-2022-1614-0869396

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:21
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:42:25

FDA-CBER-2022-1614-0869397

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:21
User entered '17 Aug 2020'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:42:25

FDA-CBER-2022-1614-0869398

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:21
User entered '09:22'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:42:25

FDA-CBER-2022-1614-0869399

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered '17 Aug 2020 09:22'	System	24 Aug 2020 21:42:25

FDA-CBER-2022-1614-0869400

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:21
User entered '67' in	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:42:25
DataPoint set to visible.	System	17 Aug 2020 15:38:33

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:21
User entered '184' lb	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:42:25
DataPoint set to visible.	System	17 Aug 2020 15:38:33

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
Amendment Manager: User entered '28.87873'	System	16 Sep 2020 23:59:32
User entered '28.9'	System	24 Aug 2020 21:42:25
DataPoint set to visible.	System	17 Aug 2020 15:38:33

FDA-CBER-2022-1614-0869403

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'kg/m2'	System	24 Aug 2020 21:42:25
DataPoint set to visible.	System	17 Aug 2020 15:38:33

FDA-CBER-2022-1614-0869404

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:21
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:42:25

FDA-CBER-2022-1614-0869405

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:21
User entered empty.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:42:25

FDA-CBER-2022-1614-0869406

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:21
User entered empty.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:42:25

FDA-CBER-2022-1614-0869407

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:21
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:42:25

FDA-CBER-2022-1614-0869408

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'bpm'	System	24 Aug 2020 21:42:25

FDA-CBER-2022-1614-0869409

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:21
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:42:25

FDA-CBER-2022-1614-0869410

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'breaths/min'	System	24 Aug 2020 21:42:25

FDA-CBER-2022-1614-0869411

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:21
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:42:25

FDA-CBER-2022-1614-0869412

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'mmHg'	System	24 Aug 2020 21:42:25

FDA-CBER-2022-1614-0869413

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:21
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:42:25

FDA-CBER-2022-1614-0869414

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'mmHg'	System	24 Aug 2020 21:42:25

FDA-CBER-2022-1614-0869415

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48

FDA-CBER-2022-1614-0869416

US3312095
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48

FDA-CBER-2022-1614-0869417

US3312095
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 16:57:13
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:48:34
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:43:26

FDA-CBER-2022-1614-0869418

US3312095
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 16:57:13
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:48:34
User entered '17 Aug 2020'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:43:26

FDA-CBER-2022-1614-0869419

US3312095
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 16:57:13
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:49:13
User entered '17 Aug 2020'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:43:49

FDA-CBER-2022-1614-0869420

US3312095
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 16:57:13
Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:49:13
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:43:49

FDA-CBER-2022-1614-0869421

US3312095
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 16:57:13
If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:49:13
User entered empty.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:43:49

FDA-CBER-2022-1614-0869422

US3312095
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 16:57:13
If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:49:13
User entered empty.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:43:49

FDA-CBER-2022-1614-0869423

US3312095
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 16:57:13
If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:49:13
User entered empty.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:43:49

FDA-CBER-2022-1614-0869424

US3312095
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 16:57:13
Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:49:13
User entered '0'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:43:49

FDA-CBER-2022-1614-0869425

US3312095
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 16:57:13
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:49:13
User entered empty.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:43:49

FDA-CBER-2022-1614-0869426

US3312095
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 16:57:13
Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:49:13
User entered '0'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:43:49

FDA-CBER-2022-1614-0869427

US3312095
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:41:05
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:44:25

FDA-CBER-2022-1614-0869428

US3312095
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:41:05
User entered '17 Aug 2020'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:44:25

FDA-CBER-2022-1614-0869429

US3312095
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:41:05
User entered 'Urine (URINE)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:44:25

FDA-CBER-2022-1614-0869430

US3312095
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:41:05
User entered 'Negative (NEGATIVE)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:44:25

FDA-CBER-2022-1614-0869431

US3312095
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
User closed query 'Per CDM: Was FSH sample collected is recorded as "No", however collection date and time is recorded. Please refer to eCCGs and update.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 09:37:15
Query 'Per CDM: Was FSH sample collected is recorded as "No", however collection date and time is recorded. Please refer to eCCGs and update.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	15 Sep 2020 15:31:15
User opened query 'Per CDM: Was FSH sample collected is recorded as "No", however collection date and time is recorded. Please refer to eCCGs and update.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 06:58:50
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:41:05
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:44:25

FDA-CBER-2022-1614-0869432

US3312095
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:12:46
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Un-verified.	Karol Moore (b) (4) (b) (4)	15 Sep 2020 15:31:11
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	15 Sep 2020 15:31:11
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:41:05
User entered '17 Aug 2020'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:44:25

FDA-CBER-2022-1614-0869433

US3312095
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:12:46
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Un-verified.	Karol Moore (b) (4) (b) (4)	15 Sep 2020 15:31:11
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	15 Sep 2020 15:31:11
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 16:41:05
User entered '09:32'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:44:25

FDA-CBER-2022-1614-0869434

US3312095
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered empty.	System	15 Sep 2020 15:31:11
User entered '17 Aug 2020 09:32'	System	24 Aug 2020 21:44:25

FDA-CBER-2022-1614-0869435

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13
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 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:01
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

FDA-CBER-2022-1614-0869436

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13
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 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:01
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

FDA-CBER-2022-1614-0869437

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13
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 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:01
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

FDA-CBER-2022-1614-0869438

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13
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 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:01
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13
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 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:01
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

FDA-CBER-2022-1614-0869440

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13
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 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:01
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13
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 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:01
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13
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 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:01
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

FDA-CBER-2022-1614-0869443

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13
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 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:01
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

FDA-CBER-2022-1614-0869444

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13
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 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:01
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

FDA-CBER-2022-1614-0869445

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13
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 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:01
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:01
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

FDA-CBER-2022-1614-0869447

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:01
User entered empty.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

FDA-CBER-2022-1614-0869448

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
User entered '0'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

FDA-CBER-2022-1614-0869449

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:01
User entered '0'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

FDA-CBER-2022-1614-0869450

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13

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 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:01
User entered '0'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

FDA-CBER-2022-1614-0869451

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13
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 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:01
User entered '0'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13

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 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:01
User entered '0'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

FDA-CBER-2022-1614-0869453

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:01
User entered '0'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

FDA-CBER-2022-1614-0869454

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
User entered '1'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

FDA-CBER-2022-1614-0869455

US3312095
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:57:13
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:47:01
User entered 'resides in community with ongoing person to person transmission'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:45:13

FDA-CBER-2022-1614-0869456

US3312095
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:49:53
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:38:44

FDA-CBER-2022-1614-0869457

US3312095
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:49:53
User entered '17 Aug 2020'	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:38:44

FDA-CBER-2022-1614-0869458

US3312095
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
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 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:49:53
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:38:44

FDA-CBER-2022-1614-0869459

US3312095
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'VISIT1'	System	17 Aug 2020 15:38:44

FDA-CBER-2022-1614-0869460

US3312095
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:57:13
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:05
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	17 Aug 2020 15:14:53

FDA-CBER-2022-1614-0869461

US3312095
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:57:13
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:05
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:57:41
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:57:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 15:14:53
User entered '104589' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	17 Aug 2020 15:14:53

FDA-CBER-2022-1614-0869462

US3312095
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:57:13
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:05
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	17 Aug 2020 15:14:53

FDA-CBER-2022-1614-0869463

US3312095

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

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)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:05
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:38:59

US3312095

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

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)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:05
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:38:59

US3312095
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:57:13
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:05
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:38:59

FDA-CBER-2022-1614-0869466

US3312095
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:57:13
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:05
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:38:59

FDA-CBER-2022-1614-0869467

US3312095
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:57:13
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:05
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:38:59

FDA-CBER-2022-1614-0869468

US3312095
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:57:13
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:05
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:32:32
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:22:32
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:36:41

FDA-CBER-2022-1614-0869469

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:57:13
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:57:13
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869471

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:57:13
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:57:13
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869473

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User accepted default value 'Pre-Dose (PREDOSE)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869474

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered '17 Aug 2020'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869476

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered '09:22'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869477

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered '17 Aug 2020 09:22'	System	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869478

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered '98.0' F	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869479

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered 'Oral (Oral)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869480

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered empty.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869481

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered '58'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869482

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'bpm'	System	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869483

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered '14'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869484

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'breaths/min'	System	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869485

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered '109'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869486

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'mmHg'	System	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869487

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
User closed query 'Per CDM: Please indicate if NCS or CS and report AE if necessary. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 11:46:16
Query 'Per CDM: Please indicate if NCS or CS and report AE if necessary. Thank you.' answered with 'Correct as entered NCS. Not an AE. Per protocol toxicity table, diastolic blood pressure not defined.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 19:51:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User opened query 'Per CDM: Please indicate if NCS or CS and report AE if necessary. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:50:23
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)	24 Sep 2020 18:49:04
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 'CORRECT AS ENTERED. PER PROTOCOL TOXICITY TABLE DIASTOLIC BLOOD PRESSURE IS NOT DEFINED' (Site from System).	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:32:25
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 23:59:32
User entered '58'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869488

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'mmHg'	System	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869489

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:57:13
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869490

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:57:13
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869491

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User accepted default value 'Post-Dose (POSTDOSE)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869492

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869493

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered '17 Aug 2020'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869494

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered '11:04'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869495

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered '17 Aug 2020 11:04'	System	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869496

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered '97.6' F	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869497

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered 'Oral (Oral)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869498

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered empty.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869499

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered '55'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'bpm'	System	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869501

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered '14'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'breaths/min'	System	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869503

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered '116'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869504

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'mmHg'	System	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869505

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:51:30
User entered '71'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:27

US3312095
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'mmHg'	System	24 Aug 2020 21:47:27

FDA-CBER-2022-1614-0869507

US3312095
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 16:57:13
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:48:40
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:35

FDA-CBER-2022-1614-0869508

US3312095
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 16:57:13
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:48:40
User entered empty.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:47:35

FDA-CBER-2022-1614-0869509

US3312095
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:49
User closed query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 09:37:09
Query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	15 Sep 2020 15:08:12
User entered 'No (N)' reason for change: Per Query Resolution	Karol Moore (b) (4) (b) (4)	15 Sep 2020 15:08:08
User opened query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 11:51:08
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:48:21

FDA-CBER-2022-1614-0869510

US3312095
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:49
User entered empty; reason for change Per Query Resolution	Karol Moore (b) (4) (b) (4)	15 Sep 2020 15:08:08
User entered '17 Aug 2020'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:48:21

FDA-CBER-2022-1614-0869511

US3312095
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:49
User entered empty; reason for change Per Query Resolution	Karol Moore (b) (4) (b) (4)	15 Sep 2020 15:08:08
User entered 'Urine (URINE)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:48:21

FDA-CBER-2022-1614-0869512

US3312095
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:49
User entered empty; reason for change Per Query Resolution	Karol Moore (b) (4) (b) (4)	15 Sep 2020 15:08:08
User entered 'Negative (NEGATIVE)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:48:21

FDA-CBER-2022-1614-0869513

US3312095
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:49
User entered empty; reason for change Per Query Resolution	Karol Moore (b) (4) (b) (4)	15 Sep 2020 15:08:08
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:48:21

FDA-CBER-2022-1614-0869514

US3312095
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:49
User entered empty; reason for change Per Query Resolution	Karol Moore (b) (4) (b) (4)	15 Sep 2020 15:08:17
User entered ' Aug ' (non-conformant).	Karol Moore (b) (4) (b) (4)	15 Sep 2020 15:08:08
User entered '17 Aug 2020'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:48:21

FDA-CBER-2022-1614-0869515

US3312095
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:49
User entered empty; reason for change Per Query Resolution	Karol Moore (b) (4) (b) (4)	15 Sep 2020 15:08:08
User entered '09:32'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:48:21

FDA-CBER-2022-1614-0869516

US3312095
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered empty.	System	15 Sep 2020 15:08:08
User entered '17 Aug 2020 09:32'	System	24 Aug 2020 21:48:21

FDA-CBER-2022-1614-0869517

US3312095
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:57:13
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:14
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869518

US3312095
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:57:13
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:14
User entered empty.	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869519

US3312095
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:57:13

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:14
User entered empty.	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869520

US3312095
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:57:13
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869521

US3312095
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:57:13
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:14
User entered '17 Aug 2020'	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869522

US3312095
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:57:13
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:14
User entered '10:33'	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869523

US3312095
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:57:13
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered '17 Aug 2020 10:33'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869524

US3312095
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:57:13
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:14
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4) (b) (4)	17 Aug 2020 15:39:39

US3312095
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:57:13
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:14
User entered 'ONCE'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869526

US3312095
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:57:13
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869527

US3312095
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:57:13
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:27
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:49:03

US3312095
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:57:13
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:27
User entered '17 Aug 2020'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:49:03

FDA-CBER-2022-1614-0869529

US3312095
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:57:13
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:27
User entered '09:53'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:49:03

FDA-CBER-2022-1614-0869530

US3312095
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:57:13
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered '17 Aug 2020 09:53'	System	24 Aug 2020 21:49:03

FDA-CBER-2022-1614-0869531

US3312095
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 16:57:13
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:33
User entered '17 Aug 2020'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:49:16

FDA-CBER-2022-1614-0869532

US3312095
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:57:13
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:49:16

FDA-CBER-2022-1614-0869533

US3312095
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:57:13
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:33
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:49:16

FDA-CBER-2022-1614-0869534

US3312095
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:57:13
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:33
User entered '09:46'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:49:16

FDA-CBER-2022-1614-0869535

US3312095
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:57:13
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered '17 Aug 2020 09:46'	System	24 Aug 2020 21:49:16

FDA-CBER-2022-1614-0869536

US3312095
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:57:13
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:49:16

FDA-CBER-2022-1614-0869537

US3312095
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:57:13
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:33
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:49:16

FDA-CBER-2022-1614-0869538

US3312095
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:57:13
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:33
User entered empty.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:49:16

FDA-CBER-2022-1614-0869539

US3312095
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:57:13
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered empty.	System	24 Aug 2020 21:49:16

FDA-CBER-2022-1614-0869540

US3312095
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:50:38
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:49:21

US3312095
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered '1'	System	24 Aug 2020 21:49:21

FDA-CBER-2022-1614-0869542

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869543

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T11:06:13', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '94919796-9dbc-4036-ae4b-4407ded83087'	System	17 Aug 2020 16:06:49
User entered 'Yes (Y)'	System	17 Aug 2020 16:06:49

FDA-CBER-2022-1614-0869544

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T11:06:36', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '94919796-9dbc-4036-ae4b-4407ded83087'	System	17 Aug 2020 16:06:49
User entered '97.6'	System	17 Aug 2020 16:06:49

FDA-CBER-2022-1614-0869545

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T11:06:40', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '94919796-9dbc-4036-ae4b-4407ded83087'	System	17 Aug 2020 16:06:49
User entered 'No (N)'	System	17 Aug 2020 16:06:49

FDA-CBER-2022-1614-0869546

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T11:06:43', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '94919796-9dbc-4036-ae4b-4407ded83087'	System	17 Aug 2020 16:06:49
User entered '17 Aug 2020 11:06'	System	17 Aug 2020 16:06:49

FDA-CBER-2022-1614-0869547

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '17 Aug 2020 10:53'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869548

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '17 Aug 2020 13:23'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869549

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869550

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T21:04:01', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'b63493e2-52f2-464d-8412-783f8daf9fc6'	System	18 Aug 2020 02:05:19
User entered 'Yes (Y)'	System	18 Aug 2020 02:05:19

FDA-CBER-2022-1614-0869551

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T21:05:11', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'b63493e2-52f2-464d-8412-783f8daf9fc6'	System	18 Aug 2020 02:05:19
User entered '97.7'	System	18 Aug 2020 02:05:19

FDA-CBER-2022-1614-0869552

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T21:05:14', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'b63493e2-52f2-464d-8412-783f8daf9fc6'	System	18 Aug 2020 02:05:19
User entered 'No (N)'	System	18 Aug 2020 02:05:19

FDA-CBER-2022-1614-0869553

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T21:05:16', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'b63493e2-52f2-464d-8412-783f8daf9fc6'	System	18 Aug 2020 02:05:19
User entered '17 Aug 2020 21:05'	System	18 Aug 2020 02:05:19

FDA-CBER-2022-1614-0869554

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '17 Aug 2020 14:18'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869555

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869556

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 2'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869557

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:57:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-18T22:21:57', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'b8cedf9f-eefc-4359-96be-51129af8ab42'	System	19 Aug 2020 03:22:07
User entered 'Yes (Y)'	System	19 Aug 2020 03:22:07

FDA-CBER-2022-1614-0869558

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:57:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-18T22:22:01', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'b8cedf9f-eefc-4359-96be-51129af8ab42'	System	19 Aug 2020 03:22:07
User entered '97.8'	System	19 Aug 2020 03:22:07

FDA-CBER-2022-1614-0869559

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:57:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-18T22:22:03', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'b8cedf9f-eefc-4359-96be-51129af8ab42'	System	19 Aug 2020 03:22:07
User entered 'No (N)'	System	19 Aug 2020 03:22:07

FDA-CBER-2022-1614-0869560

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-18T22:22:06', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'b8cedf9f-eefc-4359-96be-51129af8ab42'	System	19 Aug 2020 03:22:07
User entered '18 Aug 2020 22:22'	System	19 Aug 2020 03:22:07

FDA-CBER-2022-1614-0869561

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869562

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869563

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 3'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869564

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:57:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-19T22:54:40', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd3fb385c-6de0-45c1-bc89-f3fb733195f2'	System	20 Aug 2020 03:54:48
User entered 'Yes (Y)'	System	20 Aug 2020 03:54:48

FDA-CBER-2022-1614-0869565

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:57:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-19T22:54:43', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd3fb385c-6de0-45c1-bc89-f3fb733195f2'	System	20 Aug 2020 03:54:48
User entered '97.7'	System	20 Aug 2020 03:54:48

FDA-CBER-2022-1614-0869566

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:57:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-19T22:54:45', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd3fb385c-6de0-45c1-bc89-f3fb733195f2'	System	20 Aug 2020 03:54:48
User entered 'No (N)'	System	20 Aug 2020 03:54:48

FDA-CBER-2022-1614-0869567

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-19T22:54:47', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd3fb385c-6de0-45c1-bc89-f3fb733195f2'	System	20 Aug 2020 03:54:48
User entered '19 Aug 2020 22:54'	System	20 Aug 2020 03:54:48

FDA-CBER-2022-1614-0869568

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869569

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869570

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 4'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869571

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:57:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-20T18:46:30', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '9e11fe17-8bee-4833-9919-2c3ac6c468d0'	System	20 Aug 2020 23:46:44
User entered 'Yes (Y)'	System	20 Aug 2020 23:46:44

FDA-CBER-2022-1614-0869572

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:57:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-20T18:46:35', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '9e11fe17-8bee-4833-9919-2c3ac6c468d0'	System	20 Aug 2020 23:46:44
User entered '97.2'	System	20 Aug 2020 23:46:44

FDA-CBER-2022-1614-0869573

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:57:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-20T18:46:36', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '9e11fe17-8bee-4833-9919-2c3ac6c468d0'	System	20 Aug 2020 23:46:44
User entered 'No (N)'	System	20 Aug 2020 23:46:44

FDA-CBER-2022-1614-0869574

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-20T18:46:38', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '9e11fe17-8bee-4833-9919-2c3ac6c468d0'	System	20 Aug 2020 23:46:44
User entered '20 Aug 2020 18:46'	System	20 Aug 2020 23:46:44

FDA-CBER-2022-1614-0869575

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869576

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869577

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 5'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869578

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:57:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-22T00:43:36', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ff058e46-d686-47a7-b5a3-4cd0c3bf9a41'	System	22 Aug 2020 05:43:48
User entered 'Yes (Y)'	System	22 Aug 2020 05:43:48

FDA-CBER-2022-1614-0869579

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:57:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-22T00:43:40', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ff058e46-d686-47a7-b5a3-4cd0c3bf9a41'	System	22 Aug 2020 05:43:48
User entered '97.7'	System	22 Aug 2020 05:43:48

FDA-CBER-2022-1614-0869580

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:57:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-22T00:43:42', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ff058e46-d686-47a7-b5a3-4cd0c3bf9a41'	System	22 Aug 2020 05:43:48
User entered 'No (N)'	System	22 Aug 2020 05:43:48

FDA-CBER-2022-1614-0869581

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-22T00:43:43', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ff058e46-d686-47a7-b5a3-4cd0c3bf9a41'	System	22 Aug 2020 05:43:48
User entered '22 Aug 2020 00:43'	System	22 Aug 2020 05:43:48

FDA-CBER-2022-1614-0869582

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869583

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869584

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 6'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869585

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:57:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T08:13:58', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '0ad8d8a7-fcf6-4e85-9571-8fbac36c4dc3'	System	23 Aug 2020 13:14:14
User entered 'Yes (Y)'	System	23 Aug 2020 13:14:14

FDA-CBER-2022-1614-0869586

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:57:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T08:14:04', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '0ad8d8a7-fcf6-4e85-9571-8fbac36c4dc3'	System	23 Aug 2020 13:14:14
User entered '98.7'	System	23 Aug 2020 13:14:14

FDA-CBER-2022-1614-0869587

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:57:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T08:14:09', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '0ad8d8a7-fcf6-4e85-9571-8fbac36c4dc3'	System	23 Aug 2020 13:14:14
User entered 'No (N)'	System	23 Aug 2020 13:14:14

FDA-CBER-2022-1614-0869588

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T08:14:12', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '0ad8d8a7-fcf6-4e85-9571-8fbac36c4dc3'	System	23 Aug 2020 13:14:14
User entered '23 Aug 2020 08:14'	System	23 Aug 2020 13:14:14

FDA-CBER-2022-1614-0869589

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869590

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869591

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 7'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869592

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:57:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T23:41:27', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ac25213c-0ace-4cd4-ba29-336a147b8bbd'	System	24 Aug 2020 04:41:38
User entered 'Yes (Y)'	System	24 Aug 2020 04:41:38

FDA-CBER-2022-1614-0869593

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:57:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T23:41:32', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ac25213c-0ace-4cd4-ba29-336a147b8bbd'	System	24 Aug 2020 04:41:38
User entered '98.2'	System	24 Aug 2020 04:41:38

FDA-CBER-2022-1614-0869594

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:57:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T23:41:34', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ac25213c-0ace-4cd4-ba29-336a147b8bbd'	System	24 Aug 2020 04:41:38
User entered 'No (N)'	System	24 Aug 2020 04:41:38

FDA-CBER-2022-1614-0869595

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T23:41:36', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ac25213c-0ace-4cd4-ba29-336a147b8bbd'	System	24 Aug 2020 04:41:38
User entered '23 Aug 2020 23:41'	System	24 Aug 2020 04:41:38

FDA-CBER-2022-1614-0869596

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869597

US3312095
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869598

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869599

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T11:06:48', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e3489e61-fad6-441e-9764-385d10f000ad'	System	17 Aug 2020 16:07:08
User entered 'None (1)'	System	17 Aug 2020 16:07:08

FDA-CBER-2022-1614-0869600

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T11:06:50', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e3489e61-fad6-441e-9764-385d10f000ad'	System	17 Aug 2020 16:07:08
User entered 'No (N)'	System	17 Aug 2020 16:07:08

FDA-CBER-2022-1614-0869601

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T11:06:52', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e3489e61-fad6-441e-9764-385d10f000ad'	System	17 Aug 2020 16:07:08
User entered 'No (N)'	System	17 Aug 2020 16:07:08

FDA-CBER-2022-1614-0869602

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T11:06:55', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e3489e61-fad6-441e-9764-385d10f000ad'	System	17 Aug 2020 16:07:08
User entered 'None (1)'	System	17 Aug 2020 16:07:08

FDA-CBER-2022-1614-0869603

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T11:07:02', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e3489e61-fad6-441e-9764-385d10f000ad'	System	17 Aug 2020 16:07:08
User entered '17 Aug 2020 11:07'	System	17 Aug 2020 16:07:08

FDA-CBER-2022-1614-0869604

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '17 Aug 2020 10:53'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869605

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '17 Aug 2020 13:23'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869606

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869607

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T21:05:21', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'da60ee6e-e787-4391-b9c8-5fe7b0934ccd'	System	18 Aug 2020 02:05:31
User entered 'None (1)'	System	18 Aug 2020 02:05:31

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T21:05:23', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'da60ee6e-e787-4391-b9c8-5fe7b0934ccd'	System	18 Aug 2020 02:05:31
User entered 'No (N)'	System	18 Aug 2020 02:05:31

FDA-CBER-2022-1614-0869609

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T21:05:25', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'da60ee6e-e787-4391-b9c8-5fe7b0934ccd'	System	18 Aug 2020 02:05:31
User entered 'No (N)'	System	18 Aug 2020 02:05:31

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T21:05:27', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'da60ee6e-e787-4391-b9c8-5fe7b0934ccd'	System	18 Aug 2020 02:05:31
User entered 'None (1)'	System	18 Aug 2020 02:05:31

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T21:05:29', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'da60ee6e-e787-4391-b9c8-5fe7b0934ccd'	System	18 Aug 2020 02:05:31
User entered '17 Aug 2020 21:05'	System	18 Aug 2020 02:05:31

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '17 Aug 2020 14:18'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869613

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869614

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 2'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869615

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:57:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-18T19:56:49', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '9817dc13-ea9c-452c-a566-2c701a621e96'	System	19 Aug 2020 00:57:01
User entered 'None (1)'	System	19 Aug 2020 00:57:01

FDA-CBER-2022-1614-0869616

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:57:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-18T19:56:52', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '9817dc13-ea9c-452c-a566-2c701a621e96'	System	19 Aug 2020 00:57:01
User entered 'No (N)'	System	19 Aug 2020 00:57:01

FDA-CBER-2022-1614-0869617

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:57:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-18T19:56:55', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '9817dc13-ea9c-452c-a566-2c701a621e96'	System	19 Aug 2020 00:57:01
User entered 'No (N)'	System	19 Aug 2020 00:57:01

FDA-CBER-2022-1614-0869618

US3312095

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:57:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-18T19:56:56', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '9817dc13-ea9c-452c-a566-2c701a621e96'	System	19 Aug 2020 00:57:01
User entered 'None (1)'	System	19 Aug 2020 00:57:01

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-18T19:56:58', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '9817dc13-ea9c-452c-a566-2c701a621e96'	System	19 Aug 2020 00:57:01
User entered '18 Aug 2020 19:56'	System	19 Aug 2020 00:57:01

FDA-CBER-2022-1614-0869620

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869621

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869622

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 3'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869623

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:57:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-19T22:54:51', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '08a9dd56-9769-4410-aecd-949a39377477'	System	20 Aug 2020 03:56:07
User entered 'None (1)'	System	20 Aug 2020 03:56:07

FDA-CBER-2022-1614-0869624

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:57:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-19T22:54:58', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '08a9dd56-9769-4410-aecd-949a39377477'	System	20 Aug 2020 03:56:07
User entered 'No (N)'	System	20 Aug 2020 03:56:07

FDA-CBER-2022-1614-0869625

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:57:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-19T22:55:00', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '08a9dd56-9769-4410-aecd-949a39377477'	System	20 Aug 2020 03:56:07
User entered 'No (N)'	System	20 Aug 2020 03:56:07

FDA-CBER-2022-1614-0869626

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:57:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-19T22:55:59', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '08a9dd56-9769-4410-aecd-949a39377477'	System	20 Aug 2020 03:56:07
User entered 'None (1)'	System	20 Aug 2020 03:56:07

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-19T22:56:01', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '08a9dd56-9769-4410-aecd-949a39377477'	System	20 Aug 2020 03:56:07
User entered '19 Aug 2020 22:56'	System	20 Aug 2020 03:56:07

FDA-CBER-2022-1614-0869628

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869629

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869630

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 4'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869631

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:57:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-20T18:47:13', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '5d7cbbd3-174e-4a16-83df-96830b0e2117'	System	20 Aug 2020 23:47:22
User entered 'None (1)'	System	20 Aug 2020 23:47:22

FDA-CBER-2022-1614-0869632

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:57:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-20T18:47:14', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '5d7cbbd3-174e-4a16-83df-96830b0e2117'	System	20 Aug 2020 23:47:22
User entered 'No (N)'	System	20 Aug 2020 23:47:22

FDA-CBER-2022-1614-0869633

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:57:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-20T18:47:16', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '5d7cbbd3-174e-4a16-83df-96830b0e2117'	System	20 Aug 2020 23:47:22
User entered 'No (N)'	System	20 Aug 2020 23:47:22

FDA-CBER-2022-1614-0869634

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:57:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-20T18:47:17', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '5d7cbbd3-174e-4a16-83df-96830b0e2117'	System	20 Aug 2020 23:47:22
User entered 'None (1)'	System	20 Aug 2020 23:47:22

FDA-CBER-2022-1614-0869635

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-20T18:47:19', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '5d7cbbd3-174e-4a16-83df-96830b0e2117'	System	20 Aug 2020 23:47:22
User entered '20 Aug 2020 18:47'	System	20 Aug 2020 23:47:22

FDA-CBER-2022-1614-0869636

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869637

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869638

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 5'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869639

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:57:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-22T00:43:46', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ea7d3762-f82f-4225-a3dc-fe18c457fc8c'	System	22 Aug 2020 05:43:57
User entered 'None (1)'	System	22 Aug 2020 05:43:57

FDA-CBER-2022-1614-0869640

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:57:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-22T00:43:49', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ea7d3762-f82f-4225-a3dc-fe18c457fc8c'	System	22 Aug 2020 05:43:57
User entered 'No (N)'	System	22 Aug 2020 05:43:57

FDA-CBER-2022-1614-0869641

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:57:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-22T00:43:50', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ea7d3762-f82f-4225-a3dc-fe18c457fc8c'	System	22 Aug 2020 05:43:57
User entered 'No (N)'	System	22 Aug 2020 05:43:57

FDA-CBER-2022-1614-0869642

US3312095

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-22T00:43:51', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ea7d3762-f82f-4225-a3dc-fe18c457fc8c'	System	22 Aug 2020 05:43:57
User entered 'None (1)'	System	22 Aug 2020 05:43:57

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-22T00:43:53', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ea7d3762-f82f-4225-a3dc-fe18c457fc8c'	System	22 Aug 2020 05:43:57
User entered '22 Aug 2020 00:43'	System	22 Aug 2020 05:43:57

FDA-CBER-2022-1614-0869644

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869645

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869646

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 6'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869647

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:57:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T08:14:35', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '9c72ed0b-6b10-4e4a-8ae1-5372a2e8d6b2'	System	23 Aug 2020 13:14:48
User entered 'None (1)'	System	23 Aug 2020 13:14:48

FDA-CBER-2022-1614-0869648

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:57:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T08:14:39', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '9c72ed0b-6b10-4e4a-8ae1-5372a2e8d6b2'	System	23 Aug 2020 13:14:48
User entered 'No (N)'	System	23 Aug 2020 13:14:48

FDA-CBER-2022-1614-0869649

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:57:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T08:14:40', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '9c72ed0b-6b10-4e4a-8ae1-5372a2e8d6b2'	System	23 Aug 2020 13:14:48
User entered 'No (N)'	System	23 Aug 2020 13:14:48

FDA-CBER-2022-1614-0869650

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:57:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T08:14:43', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '9c72ed0b-6b10-4e4a-8ae1-5372a2e8d6b2'	System	23 Aug 2020 13:14:48
User entered 'None (1)'	System	23 Aug 2020 13:14:48

FDA-CBER-2022-1614-0869651

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T08:14:45', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '9c72ed0b-6b10-4e4a-8ae1-5372a2e8d6b2'	System	23 Aug 2020 13:14:48
User entered '23 Aug 2020 08:14'	System	23 Aug 2020 13:14:48

FDA-CBER-2022-1614-0869652

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869653

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869654

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 7'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869655

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:57:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T23:41:39', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c30b8242-baca-4e8b-adff-3ade5f0620bd'	System	24 Aug 2020 04:41:49
User entered 'None (1)'	System	24 Aug 2020 04:41:49

FDA-CBER-2022-1614-0869656

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:57:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T23:41:41', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c30b8242-baca-4e8b-adff-3ade5f0620bd'	System	24 Aug 2020 04:41:49
User entered 'No (N)'	System	24 Aug 2020 04:41:49

FDA-CBER-2022-1614-0869657

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:57:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T23:41:43', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c30b8242-baca-4e8b-adff-3ade5f0620bd'	System	24 Aug 2020 04:41:49
User entered 'No (N)'	System	24 Aug 2020 04:41:49

FDA-CBER-2022-1614-0869658

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:57:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T23:41:45', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c30b8242-baca-4e8b-adff-3ade5f0620bd'	System	24 Aug 2020 04:41:49
User entered 'None (1)'	System	24 Aug 2020 04:41:49

FDA-CBER-2022-1614-0869659

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T23:41:47', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c30b8242-baca-4e8b-adff-3ade5f0620bd'	System	24 Aug 2020 04:41:49
User entered '23 Aug 2020 23:41'	System	24 Aug 2020 04:41:49

FDA-CBER-2022-1614-0869660

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869661

US3312095
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869662

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869663

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T11:07:11', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '75ec995b-1c3b-4e73-b235-9b452fe225fb'	System	17 Aug 2020 16:07:26
User entered 'None (0)'	System	17 Aug 2020 16:07:26

FDA-CBER-2022-1614-0869664

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T11:07:12', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '75ec995b-1c3b-4e73-b235-9b452fe225fb'	System	17 Aug 2020 16:07:26
User entered 'None (0)'	System	17 Aug 2020 16:07:26

FDA-CBER-2022-1614-0869665

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T11:07:14', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '75ec995b-1c3b-4e73-b235-9b452fe225fb'	System	17 Aug 2020 16:07:26
User entered 'None (0)'	System	17 Aug 2020 16:07:26

FDA-CBER-2022-1614-0869666

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T11:07:15', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '75ec995b-1c3b-4e73-b235-9b452fe225fb'	System	17 Aug 2020 16:07:26
User entered 'None (0)'	System	17 Aug 2020 16:07:26

FDA-CBER-2022-1614-0869667

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T11:07:18', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '75ec995b-1c3b-4e73-b235-9b452fe225fb'	System	17 Aug 2020 16:07:26
User entered 'None (0)'	System	17 Aug 2020 16:07:26

FDA-CBER-2022-1614-0869668

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T11:07:19', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '75ec995b-1c3b-4e73-b235-9b452fe225fb'	System	17 Aug 2020 16:07:26
User entered 'None (0)'	System	17 Aug 2020 16:07:26

FDA-CBER-2022-1614-0869669

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T11:07:21', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '75ec995b-1c3b-4e73-b235-9b452fe225fb'	System	17 Aug 2020 16:07:26
User entered 'No (N)'	System	17 Aug 2020 16:07:26

FDA-CBER-2022-1614-0869670

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T11:07:23', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '75ec995b-1c3b-4e73-b235-9b452fe225fb'	System	17 Aug 2020 16:07:26
User entered '17 Aug 2020 11:07'	System	17 Aug 2020 16:07:26

FDA-CBER-2022-1614-0869671

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '17 Aug 2020 10:53'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869672

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '17 Aug 2020 13:23'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869673

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869674

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T21:05:33', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e3584691-80f1-4f67-8aa7-b51c18aba2cc'	System	18 Aug 2020 02:05:59
User entered 'None (0)'	System	18 Aug 2020 02:05:59

FDA-CBER-2022-1614-0869675

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T21:05:35', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e3584691-80f1-4f67-8aa7-b51c18aba2cc'	System	18 Aug 2020 02:05:59
User entered 'None (0)'	System	18 Aug 2020 02:05:59

FDA-CBER-2022-1614-0869676

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T21:05:36', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e3584691-80f1-4f67-8aa7-b51c18aba2cc'	System	18 Aug 2020 02:05:59
User entered 'None (0)'	System	18 Aug 2020 02:05:59

FDA-CBER-2022-1614-0869677

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T21:05:38', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e3584691-80f1-4f67-8aa7-b51c18aba2cc'	System	18 Aug 2020 02:05:59
User entered 'None (0)'	System	18 Aug 2020 02:05:59

FDA-CBER-2022-1614-0869678

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T21:05:39', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e3584691-80f1-4f67-8aa7-b51c18aba2cc'	System	18 Aug 2020 02:05:59
User entered 'None (0)'	System	18 Aug 2020 02:05:59

FDA-CBER-2022-1614-0869679

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T21:05:43', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e3584691-80f1-4f67-8aa7-b51c18aba2cc'	System	18 Aug 2020 02:05:59
User entered 'None (0)'	System	18 Aug 2020 02:05:59

FDA-CBER-2022-1614-0869680

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T21:05:52', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e3584691-80f1-4f67-8aa7-b51c18aba2cc'	System	18 Aug 2020 02:05:59
User entered 'No (N)'	System	18 Aug 2020 02:05:59

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-17T21:05:57', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e3584691-80f1-4f67-8aa7-b51c18aba2cc'	System	18 Aug 2020 02:05:59
User entered '17 Aug 2020 21:05'	System	18 Aug 2020 02:05:59

FDA-CBER-2022-1614-0869682

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '17 Aug 2020 14:18'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869683

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869684

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 2'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869685

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-18T19:57:00', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'a9a71003-2a07-4bda-aa22-ae2b97c4475e'	System	19 Aug 2020 00:57:14
User entered 'None (0)'	System	19 Aug 2020 00:57:14

FDA-CBER-2022-1614-0869686

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-18T19:57:02', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'a9a71003-2a07-4bda-aa22-ae2b97c4475e'	System	19 Aug 2020 00:57:14
User entered 'None (0)'	System	19 Aug 2020 00:57:14

FDA-CBER-2022-1614-0869687

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-18T19:57:03', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'a9a71003-2a07-4bda-aa22-ae2b97c4475e'	System	19 Aug 2020 00:57:14
User entered 'None (0)'	System	19 Aug 2020 00:57:14

FDA-CBER-2022-1614-0869688

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-18T19:57:04', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'a9a71003-2a07-4bda-aa22-ae2b97c4475e'	System	19 Aug 2020 00:57:14
User entered 'None (0)'	System	19 Aug 2020 00:57:14

FDA-CBER-2022-1614-0869689

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-18T19:57:05', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'a9a71003-2a07-4bda-aa22-ae2b97c4475e'	System	19 Aug 2020 00:57:14
User entered 'None (0)'	System	19 Aug 2020 00:57:14

FDA-CBER-2022-1614-0869690

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-18T19:57:06', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'a9a71003-2a07-4bda-aa22-ae2b97c4475e'	System	19 Aug 2020 00:57:14
User entered 'None (0)'	System	19 Aug 2020 00:57:14

FDA-CBER-2022-1614-0869691

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-18T19:57:09', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'a9a71003-2a07-4bda-aa22-ae2b97c4475e'	System	19 Aug 2020 00:57:14
User entered 'No (N)'	System	19 Aug 2020 00:57:14

FDA-CBER-2022-1614-0869692

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-18T19:57:11', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'a9a71003-2a07-4bda-aa22-ae2b97c4475e'	System	19 Aug 2020 00:57:14
User entered '18 Aug 2020 19:57'	System	19 Aug 2020 00:57:14

FDA-CBER-2022-1614-0869693

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869694

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869695

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 3'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869696

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-19T22:56:04', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd6fe158c-088a-42c3-96ac-781a85133788'	System	20 Aug 2020 03:56:18
User entered 'None (0)'	System	20 Aug 2020 03:56:18

FDA-CBER-2022-1614-0869697

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-19T22:56:06', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd6fe158c-088a-42c3-96ac-781a85133788'	System	20 Aug 2020 03:56:18
User entered 'None (0)'	System	20 Aug 2020 03:56:18

FDA-CBER-2022-1614-0869698

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-19T22:56:07', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd6fe158c-088a-42c3-96ac-781a85133788'	System	20 Aug 2020 03:56:18
User entered 'None (0)'	System	20 Aug 2020 03:56:18

FDA-CBER-2022-1614-0869699

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-19T22:56:08', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd6fe158c-088a-42c3-96ac-781a85133788'	System	20 Aug 2020 03:56:18
User entered 'None (0)'	System	20 Aug 2020 03:56:18

FDA-CBER-2022-1614-0869700

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-19T22:56:10', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd6fe158c-088a-42c3-96ac-781a85133788'	System	20 Aug 2020 03:56:18
User entered 'None (0)'	System	20 Aug 2020 03:56:18

FDA-CBER-2022-1614-0869701

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-19T22:56:11', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd6fe158c-088a-42c3-96ac-781a85133788'	System	20 Aug 2020 03:56:18
User entered 'None (0)'	System	20 Aug 2020 03:56:18

FDA-CBER-2022-1614-0869702

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-19T22:56:13', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd6fe158c-088a-42c3-96ac-781a85133788'	System	20 Aug 2020 03:56:18
User entered 'No (N)'	System	20 Aug 2020 03:56:18

FDA-CBER-2022-1614-0869703

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-19T22:56:15', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd6fe158c-088a-42c3-96ac-781a85133788'	System	20 Aug 2020 03:56:18
User entered '19 Aug 2020 22:56'	System	20 Aug 2020 03:56:18

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869705

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869706

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 4'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869707

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-20T18:47:07', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '77db16b7-c780-4b16-be81-39671bdbae2c'	System	20 Aug 2020 23:47:13
User entered 'No interference with activity (1)'	System	20 Aug 2020 23:47:13

FDA-CBER-2022-1614-0869708

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-20T18:46:56', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '77db16b7-c780-4b16-be81-39671bdbae2c'	System	20 Aug 2020 23:47:13
User entered 'None (0)'	System	20 Aug 2020 23:47:13

FDA-CBER-2022-1614-0869709

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-20T18:46:55', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '77db16b7-c780-4b16-be81-39671bdbae2c'	System	20 Aug 2020 23:47:13
User entered 'None (0)'	System	20 Aug 2020 23:47:13

FDA-CBER-2022-1614-0869710

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-20T18:46:54', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '77db16b7-c780-4b16-be81-39671bdbae2c'	System	20 Aug 2020 23:47:13
User entered 'None (0)'	System	20 Aug 2020 23:47:13

FDA-CBER-2022-1614-0869711

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-20T18:46:53', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '77db16b7-c780-4b16-be81-39671bdbae2c'	System	20 Aug 2020 23:47:13
User entered 'None (0)'	System	20 Aug 2020 23:47:13

FDA-CBER-2022-1614-0869712

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-20T18:46:53', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '77db16b7-c780-4b16-be81-39671bdbae2c'	System	20 Aug 2020 23:47:13
User entered 'None (0)'	System	20 Aug 2020 23:47:13

FDA-CBER-2022-1614-0869713

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-20T18:46:52', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '77db16b7-c780-4b16-be81-39671bdbae2c'	System	20 Aug 2020 23:47:13
User entered 'No (N)'	System	20 Aug 2020 23:47:13

FDA-CBER-2022-1614-0869714

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-20T18:47:10', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '77db16b7-c780-4b16-be81-39671bdbae2c'	System	20 Aug 2020 23:47:13
User entered '20 Aug 2020 18:47'	System	20 Aug 2020 23:47:13

FDA-CBER-2022-1614-0869715

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869716

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869717

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 5'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869718

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-22T00:43:56', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'daf098f3-73f1-4a70-9c85-e7f54694959e'	System	22 Aug 2020 05:44:11
User entered 'None (0)'	System	22 Aug 2020 05:44:11

FDA-CBER-2022-1614-0869719

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-22T00:43:58', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'daf098f3-73f1-4a70-9c85-e7f54694959e'	System	22 Aug 2020 05:44:11
User entered 'None (0)'	System	22 Aug 2020 05:44:11

FDA-CBER-2022-1614-0869720

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-22T00:44:00', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'daf098f3-73f1-4a70-9c85-e7f54694959e'	System	22 Aug 2020 05:44:11
User entered 'None (0)'	System	22 Aug 2020 05:44:11

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-22T00:44:01', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'daf098f3-73f1-4a70-9c85-e7f54694959e'	System	22 Aug 2020 05:44:11
User entered 'None (0)'	System	22 Aug 2020 05:44:11

FDA-CBER-2022-1614-0869722

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-22T00:44:02', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'daf098f3-73f1-4a70-9c85-e7f54694959e'	System	22 Aug 2020 05:44:11
User entered 'None (0)'	System	22 Aug 2020 05:44:11

FDA-CBER-2022-1614-0869723

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-22T00:44:03', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'daf098f3-73f1-4a70-9c85-e7f54694959e'	System	22 Aug 2020 05:44:11
User entered 'None (0)'	System	22 Aug 2020 05:44:11

FDA-CBER-2022-1614-0869724

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-22T00:44:05', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'daf098f3-73f1-4a70-9c85-e7f54694959e'	System	22 Aug 2020 05:44:11
User entered 'No (N)'	System	22 Aug 2020 05:44:11

FDA-CBER-2022-1614-0869725

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-22T00:44:09', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'daf098f3-73f1-4a70-9c85-e7f54694959e'	System	22 Aug 2020 05:44:11
User entered '22 Aug 2020 00:44'	System	22 Aug 2020 05:44:11

FDA-CBER-2022-1614-0869726

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869727

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869728

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 6'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869729

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T08:14:17', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e66128d7-1c84-4ec8-b709-0874b8fc6291'	System	23 Aug 2020 13:14:35
User entered 'No interference with activity (1)'	System	23 Aug 2020 13:14:35

FDA-CBER-2022-1614-0869730

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T08:14:20', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e66128d7-1c84-4ec8-b709-0874b8fc6291'	System	23 Aug 2020 13:14:35
User entered 'None (0)'	System	23 Aug 2020 13:14:35

FDA-CBER-2022-1614-0869731

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T08:14:21', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e66128d7-1c84-4ec8-b709-0874b8fc6291'	System	23 Aug 2020 13:14:35
User entered 'None (0)'	System	23 Aug 2020 13:14:35

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T08:14:22', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e66128d7-1c84-4ec8-b709-0874b8fc6291'	System	23 Aug 2020 13:14:35
User entered 'None (0)'	System	23 Aug 2020 13:14:35

FDA-CBER-2022-1614-0869733

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T08:14:24', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e66128d7-1c84-4ec8-b709-0874b8fc6291'	System	23 Aug 2020 13:14:35
User entered 'None (0)'	System	23 Aug 2020 13:14:35

FDA-CBER-2022-1614-0869734

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T08:14:26', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e66128d7-1c84-4ec8-b709-0874b8fc6291'	System	23 Aug 2020 13:14:35
User entered 'None (0)'	System	23 Aug 2020 13:14:35

FDA-CBER-2022-1614-0869735

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T08:14:28', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e66128d7-1c84-4ec8-b709-0874b8fc6291'	System	23 Aug 2020 13:14:35
User entered 'No (N)'	System	23 Aug 2020 13:14:35

FDA-CBER-2022-1614-0869736

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T08:14:30', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'e66128d7-1c84-4ec8-b709-0874b8fc6291'	System	23 Aug 2020 13:14:35
User entered '23 Aug 2020 08:14'	System	23 Aug 2020 13:14:35

FDA-CBER-2022-1614-0869737

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869738

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869739

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 7'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869740

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T23:41:50', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '2ccdbf04-80a0-474f-a7eb-fcf36d45ffaf'	System	24 Aug 2020 04:42:02
User entered 'None (0)'	System	24 Aug 2020 04:42:02

FDA-CBER-2022-1614-0869741

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T23:41:51', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '2ccdbf04-80a0-474f-a7eb-fcf36d45ffaf'	System	24 Aug 2020 04:42:02
User entered 'None (0)'	System	24 Aug 2020 04:42:02

FDA-CBER-2022-1614-0869742

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T23:41:52', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '2ccdbf04-80a0-474f-a7eb-fcf36d45ffaf'	System	24 Aug 2020 04:42:02
User entered 'None (0)'	System	24 Aug 2020 04:42:02

FDA-CBER-2022-1614-0869743

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T23:41:53', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '2ccdbf04-80a0-474f-a7eb-fcf36d45ffaf'	System	24 Aug 2020 04:42:02
User entered 'None (0)'	System	24 Aug 2020 04:42:02

FDA-CBER-2022-1614-0869744

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T23:41:55', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '2ccdbf04-80a0-474f-a7eb-fcf36d45ffaf'	System	24 Aug 2020 04:42:02
User entered 'None (0)'	System	24 Aug 2020 04:42:02

FDA-CBER-2022-1614-0869745

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T23:41:56', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '2ccdbf04-80a0-474f-a7eb-fcf36d45ffaf'	System	24 Aug 2020 04:42:02
User entered 'None (0)'	System	24 Aug 2020 04:42:02

FDA-CBER-2022-1614-0869746

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T23:41:58', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '2ccdbf04-80a0-474f-a7eb-fcf36d45ffaf'	System	24 Aug 2020 04:42:02
User entered 'No (N)'	System	24 Aug 2020 04:42:02

FDA-CBER-2022-1614-0869747

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-08-23T23:42:00', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '2ccdbf04-80a0-474f-a7eb-fcf36d45ffaf'	System	24 Aug 2020 04:42:02
User entered '23 Aug 2020 23:42'	System	24 Aug 2020 04:42:02

FDA-CBER-2022-1614-0869748

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869749

US3312095
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0869750

US3312095
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:35
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:49:33

FDA-CBER-2022-1614-0869751

US3312095
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:35
User entered '24 Aug 2020'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:49:33

US3312095
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:35
User entered 'Contact Made (CONTACT MADE)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:49:33

US3312095
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:35
User entered empty.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:49:33

FDA-CBER-2022-1614-0869754

US3312095
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:38
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 21:49:37

US3312095
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered '1'	System	24 Aug 2020 21:49:37

FDA-CBER-2022-1614-0869756

US3312095
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:40:04
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:29:47

US3312095
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:40:04
User entered '31 Aug 2020'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:29:47

US3312095
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:40:04
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:29:47

US3312095
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:40:04
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:29:47

FDA-CBER-2022-1614-0869760

US3312095
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:40:07
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:29:50

US3312095
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered '1'	System	07 Sep 2020 17:29:50

FDA-CBER-2022-1614-0869762

US3312095
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:40:42
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:30:10

US3312095
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:40:42
User entered '7 Sep 2020'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:30:10

FDA-CBER-2022-1614-0869764

US3312095
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:40:42
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:30:10

US3312095
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:40:42
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:30:10

FDA-CBER-2022-1614-0869766

US3312095
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:40:48
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:30:13

FDA-CBER-2022-1614-0869767

US3312095
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:48
User entered '1'	System	07 Sep 2020 17:30:13

FDA-CBER-2022-1614-0869768

US3312095
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:42:03
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 14:28:55

US3312095
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:42:03
User entered '21 Sep 2020'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 14:28:55

FDA-CBER-2022-1614-0869770

US3312095
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
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 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:42:03
User entered 'Clinic (Clinic)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 14:28:55

US3312095
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered 'VISIT2'	System	21 Sep 2020 14:28:55

FDA-CBER-2022-1614-0869772

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869773

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:20
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869774

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:20
User entered '21 Sep 2020'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869775

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:20
User entered '08:16'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869776

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered '21 Sep 2020 08:16'	System	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869777

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:20
User entered '97.9' F	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869778

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:20
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869779

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:20
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869780

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:20
User entered '70'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869781

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered 'bpm'	System	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869782

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:20
User entered '16'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered 'breaths/min'	System	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869784

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:20
User entered '130'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered 'mmHg'	System	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869786

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:20
User entered '79'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869787

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:57:13
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered 'mmHg'	System	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869788

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869789

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:20
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869790

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:20
User entered '21 Sep 2020'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869791

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:20
User entered '09:56'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869792

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered '21 Sep 2020 09:56'	System	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869793

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:20
User entered '98.0' F	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869794

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:20
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869795

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:20
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869796

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:20
User entered '63'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869797

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered 'bpm'	System	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869798

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:20
User entered '14'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869799

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered 'breaths/min'	System	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869800

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:20
User entered '140'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered 'mmHg'	System	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869802

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:20
User entered '82'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869803

US3312095
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:57:13
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered 'mmHg'	System	23 Sep 2020 19:33:18

FDA-CBER-2022-1614-0869804

US3312095
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:57:13
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:42:38
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:24

FDA-CBER-2022-1614-0869805

US3312095
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:57:13
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:42:38
User entered '21 Sep 2020'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:24

FDA-CBER-2022-1614-0869806

US3312095
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:42:59
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:37

FDA-CBER-2022-1614-0869807

US3312095
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:42:59
User entered '21 Sep 2020'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:37

FDA-CBER-2022-1614-0869808

US3312095
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:42:59
User entered 'Urine (URINE)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:37

FDA-CBER-2022-1614-0869809

US3312095
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:42:59
User entered 'Negative (NEGATIVE)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:37

FDA-CBER-2022-1614-0869810

US3312095
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:42:59
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:37

FDA-CBER-2022-1614-0869811

US3312095
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:42:59
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:37

US3312095
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:42:59
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:37

FDA-CBER-2022-1614-0869813

US3312095
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 16:57:13
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered empty.	System	23 Sep 2020 19:33:37

FDA-CBER-2022-1614-0869814

US3312095
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:57:13
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:43:10
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869815

US3312095
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:57:13
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:43:10
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869816

US3312095

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:43:10
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 14:29:29

US3312095
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:57:13
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869818

US3312095
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:57:13
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:43:10
User entered '21 Sep 2020'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869819

US3312095
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:57:13
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:43:10
User entered '09:25'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869820

US3312095
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:57:13
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered '21 Sep 2020 09:25'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869821

US3312095
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:57:13
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:43:10
User entered 'Left Arm (LEFT ARM)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869822

US3312095
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:57:13
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:43:10
User entered 'ONCE'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869823

US3312095
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:57:13
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869824

US3312095
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:57:13
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:43:52
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:51

US3312095
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:57:13
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 21SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:03:45
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 21SEP2020; however, it has not been received by GCL. Please clarify.' answered with 'check updated lab, correct as entered' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 16:37:44
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 21SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 20:14:53
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:43:52
User entered '21 Sep 2020'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:51

FDA-CBER-2022-1614-0869826

US3312095
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:57:13
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:43:52
User entered '08:47'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:33:51

FDA-CBER-2022-1614-0869827

US3312095
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:57:13
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered '21 Sep 2020 08:47'	System	23 Sep 2020 19:33:51

FDA-CBER-2022-1614-0869828

US3312095
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 16:57:13
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:43:57
User entered '21 Sep 2020'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:34:02

FDA-CBER-2022-1614-0869829

US3312095
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:57:13
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:34:02

FDA-CBER-2022-1614-0869830

US3312095
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:57:13
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:43:57
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:34:02

FDA-CBER-2022-1614-0869831

US3312095
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:57:13
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:43:57
User entered '08:41'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:34:02

FDA-CBER-2022-1614-0869832

US3312095
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:57:13
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered '21 Sep 2020 08:41'	System	23 Sep 2020 19:34:02

FDA-CBER-2022-1614-0869833

US3312095
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:57:13
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:34:02

FDA-CBER-2022-1614-0869834

US3312095
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:57:13
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:43:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:34:02

FDA-CBER-2022-1614-0869835

US3312095
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:57:13
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:43:57
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:34:02

FDA-CBER-2022-1614-0869836

US3312095
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:57:13
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered empty.	System	23 Sep 2020 19:34:02

FDA-CBER-2022-1614-0869837

US3312095
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:43:59
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 14:29:36

FDA-CBER-2022-1614-0869838

US3312095
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered '1'	System	21 Sep 2020 14:29:36

FDA-CBER-2022-1614-0869839

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869840

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T09:59:43', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '909a0366-4445-4b60-bd8f-6abdc92c77f0'	System	21 Sep 2020 15:00:09
User entered 'Yes (Y)'	System	21 Sep 2020 15:00:09

FDA-CBER-2022-1614-0869841

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T09:59:57', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '909a0366-4445-4b60-bd8f-6abdc92c77f0'	System	21 Sep 2020 15:00:09
User entered '98.0'	System	21 Sep 2020 15:00:09

FDA-CBER-2022-1614-0869842

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T10:00:01', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '909a0366-4445-4b60-bd8f-6abdc92c77f0'	System	21 Sep 2020 15:00:09
User entered 'No (N)'	System	21 Sep 2020 15:00:09

FDA-CBER-2022-1614-0869843

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T10:00:03', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '909a0366-4445-4b60-bd8f-6abdc92c77f0'	System	21 Sep 2020 15:00:09
User entered '21 Sep 2020 10:00'	System	21 Sep 2020 15:00:09

FDA-CBER-2022-1614-0869844

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '21 Sep 2020 09:45'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869845

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '21 Sep 2020 12:15'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869846

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869847

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T21:36:55', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '3fc4be9e-377c-49f7-b59a-903a883918f0'	System	22 Sep 2020 02:37:24
User entered 'Yes (Y)'	System	22 Sep 2020 02:37:24

FDA-CBER-2022-1614-0869848

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T21:36:59', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '3fc4be9e-377c-49f7-b59a-903a883918f0'	System	22 Sep 2020 02:37:24
User entered '98.6'	System	22 Sep 2020 02:37:24

FDA-CBER-2022-1614-0869849

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T21:37:18', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '3fc4be9e-377c-49f7-b59a-903a883918f0'	System	22 Sep 2020 02:37:24
User entered 'No (N)'	System	22 Sep 2020 02:37:24

FDA-CBER-2022-1614-0869850

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T21:37:20', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '3fc4be9e-377c-49f7-b59a-903a883918f0'	System	22 Sep 2020 02:37:24
User entered '21 Sep 2020 21:37'	System	22 Sep 2020 02:37:24

FDA-CBER-2022-1614-0869851

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '21 Sep 2020 13:10'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869852

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869853

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 2'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869854

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:57:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-22T15:44:13', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'eadbe713-a108-42f9-be62-c172f5345826'	System	22 Sep 2020 20:44:26
User entered 'Yes (Y)'	System	22 Sep 2020 20:44:26

FDA-CBER-2022-1614-0869855

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:57:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-22T15:44:18', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'eadbe713-a108-42f9-be62-c172f5345826'	System	22 Sep 2020 20:44:26
User entered '98.7'	System	22 Sep 2020 20:44:26

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:57:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-22T15:44:20', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'eadbe713-a108-42f9-be62-c172f5345826'	System	22 Sep 2020 20:44:26
User entered 'No (N)'	System	22 Sep 2020 20:44:26

FDA-CBER-2022-1614-0869857

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-22T15:44:22', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'eadbe713-a108-42f9-be62-c172f5345826'	System	22 Sep 2020 20:44:26
User entered '22 Sep 2020 15:44'	System	22 Sep 2020 20:44:26

FDA-CBER-2022-1614-0869858

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869859

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869860

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 3'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869861

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:57:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-23T23:59:16', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'bf5945ca-a2cd-4c4a-9630-8d96eae5151a'	System	24 Sep 2020 04:59:24
User entered 'Yes (Y)'	System	24 Sep 2020 04:59:24

FDA-CBER-2022-1614-0869862

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:57:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-23T23:59:19', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'bf5945ca-a2cd-4c4a-9630-8d96eae5151a'	System	24 Sep 2020 04:59:24
User entered '98.2'	System	24 Sep 2020 04:59:24

FDA-CBER-2022-1614-0869863

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:57:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-23T23:59:20', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'bf5945ca-a2cd-4c4a-9630-8d96eae5151a'	System	24 Sep 2020 04:59:24
User entered 'No (N)'	System	24 Sep 2020 04:59:24

FDA-CBER-2022-1614-0869864

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-23T23:59:22', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'bf5945ca-a2cd-4c4a-9630-8d96eae5151a'	System	24 Sep 2020 04:59:24
User entered '23 Sep 2020 23:59'	System	24 Sep 2020 04:59:24

FDA-CBER-2022-1614-0869865

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869866

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869867

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 4'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869868

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:57:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T06:57:59', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'fc16ce6a-ad7c-4fb4-9ee3-a209ff2ba96b'	System	25 Sep 2020 11:58:11
User entered 'Yes (Y)'	System	25 Sep 2020 11:58:11

FDA-CBER-2022-1614-0869869

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:57:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T06:58:04', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'fc16ce6a-ad7c-4fb4-9ee3-a209ff2ba96b'	System	25 Sep 2020 11:58:11
User entered '98.8'	System	25 Sep 2020 11:58:11

FDA-CBER-2022-1614-0869870

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:57:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T06:58:06', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'fc16ce6a-ad7c-4fb4-9ee3-a209ff2ba96b'	System	25 Sep 2020 11:58:11
User entered 'No (N)'	System	25 Sep 2020 11:58:11

FDA-CBER-2022-1614-0869871

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T06:58:08', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'fc16ce6a-ad7c-4fb4-9ee3-a209ff2ba96b'	System	25 Sep 2020 11:58:11
User entered '25 Sep 2020 06:58'	System	25 Sep 2020 11:58:11

FDA-CBER-2022-1614-0869872

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869873

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869874

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 5'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869875

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:57:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T23:59:11', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '6adfd8cb-c27f-4fae-9587-24c0e33c0dc2'	System	26 Sep 2020 04:59:22
User entered 'Yes (Y)'	System	26 Sep 2020 04:59:22

FDA-CBER-2022-1614-0869876

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:57:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T23:59:14', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '6adfd8cb-c27f-4fae-9587-24c0e33c0dc2'	System	26 Sep 2020 04:59:22
User entered '97.9'	System	26 Sep 2020 04:59:22

FDA-CBER-2022-1614-0869877

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:57:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T23:59:17', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '6adfd8cb-c27f-4fae-9587-24c0e33c0dc2'	System	26 Sep 2020 04:59:22
User entered 'No (N)'	System	26 Sep 2020 04:59:22

FDA-CBER-2022-1614-0869878

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T23:59:19', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '6adfd8cb-c27f-4fae-9587-24c0e33c0dc2'	System	26 Sep 2020 04:59:22
User entered '25 Sep 2020 23:59'	System	26 Sep 2020 04:59:22

FDA-CBER-2022-1614-0869879

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869880

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869881

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 6'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869882

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:57:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T09:41:22', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ffb41abd-ceb7-4634-bf2f-0b1f3192c135'	System	27 Sep 2020 14:41:31
User entered 'Yes (Y)'	System	27 Sep 2020 14:41:31

FDA-CBER-2022-1614-0869883

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:57:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T09:41:25', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ffb41abd-ceb7-4634-bf2f-0b1f3192c135'	System	27 Sep 2020 14:41:31
User entered '98.8'	System	27 Sep 2020 14:41:31

FDA-CBER-2022-1614-0869884

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:57:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T09:41:28', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ffb41abd-ceb7-4634-bf2f-0b1f3192c135'	System	27 Sep 2020 14:41:31
User entered 'No (N)'	System	27 Sep 2020 14:41:31

FDA-CBER-2022-1614-0869885

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T09:41:30', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ffb41abd-ceb7-4634-bf2f-0b1f3192c135'	System	27 Sep 2020 14:41:31
User entered '27 Sep 2020 09:41'	System	27 Sep 2020 14:41:31

FDA-CBER-2022-1614-0869886

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869887

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869888

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 7'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869889

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:57:13
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T23:59:12', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '2035c311-bc6b-4c0a-9ed6-69bbce24f90b'	System	28 Sep 2020 04:59:24
User entered 'Yes (Y)'	System	28 Sep 2020 04:59:24

FDA-CBER-2022-1614-0869890

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:57:13
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T23:59:15', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '2035c311-bc6b-4c0a-9ed6-69bbce24f90b'	System	28 Sep 2020 04:59:24
User entered '97.8'	System	28 Sep 2020 04:59:24

FDA-CBER-2022-1614-0869891

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:57:13
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T23:59:16', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '2035c311-bc6b-4c0a-9ed6-69bbce24f90b'	System	28 Sep 2020 04:59:24
User entered 'No (N)'	System	28 Sep 2020 04:59:24

FDA-CBER-2022-1614-0869892

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T23:59:18', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '2035c311-bc6b-4c0a-9ed6-69bbce24f90b'	System	28 Sep 2020 04:59:24
User entered '27 Sep 2020 23:59'	System	28 Sep 2020 04:59:24

FDA-CBER-2022-1614-0869893

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869894

US3312095
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869895

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869896

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T10:00:07', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'f743bc19-9651-4f6d-bc2b-53323e7c778c'	System	21 Sep 2020 15:00:22
User entered 'None (1)'	System	21 Sep 2020 15:00:22

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T10:00:09', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'f743bc19-9651-4f6d-bc2b-53323e7c778c'	System	21 Sep 2020 15:00:22
User entered 'No (N)'	System	21 Sep 2020 15:00:22

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T10:00:11', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'f743bc19-9651-4f6d-bc2b-53323e7c778c'	System	21 Sep 2020 15:00:22
User entered 'No (N)'	System	21 Sep 2020 15:00:22

FDA-CBER-2022-1614-0869899

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T10:00:14', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'f743bc19-9651-4f6d-bc2b-53323e7c778c'	System	21 Sep 2020 15:00:22
User entered 'None (1)'	System	21 Sep 2020 15:00:22

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T10:00:16', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'f743bc19-9651-4f6d-bc2b-53323e7c778c'	System	21 Sep 2020 15:00:22
User entered '21 Sep 2020 10:00'	System	21 Sep 2020 15:00:22

FDA-CBER-2022-1614-0869901

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '21 Sep 2020 09:45'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869902

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '21 Sep 2020 12:15'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869903

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869904

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T21:37:23', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '7ef415cd-d9f7-4dbb-9169-7fd9203b7cf6'	System	22 Sep 2020 02:37:33
User entered 'None (1)'	System	22 Sep 2020 02:37:33

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T21:37:25', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '7ef415cd-d9f7-4dbb-9169-7fd9203b7cf6'	System	22 Sep 2020 02:37:33
User entered 'No (N)'	System	22 Sep 2020 02:37:33

FDA-CBER-2022-1614-0869906

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T21:37:26', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '7ef415cd-d9f7-4dbb-9169-7fd9203b7cf6'	System	22 Sep 2020 02:37:33
User entered 'No (N)'	System	22 Sep 2020 02:37:33

FDA-CBER-2022-1614-0869907

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T21:37:28', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '7ef415cd-d9f7-4dbb-9169-7fd9203b7cf6'	System	22 Sep 2020 02:37:33
User entered 'None (1)'	System	22 Sep 2020 02:37:33

FDA-CBER-2022-1614-0869908

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T21:37:30', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '7ef415cd-d9f7-4dbb-9169-7fd9203b7cf6'	System	22 Sep 2020 02:37:33
User entered '21 Sep 2020 21:37'	System	22 Sep 2020 02:37:33

FDA-CBER-2022-1614-0869909

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '21 Sep 2020 13:10'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869910

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869911

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 2'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869912

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:57:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-22T15:44:25', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '796cb90f-1e60-4cf5-bb5c-c69149f639dd'	System	22 Sep 2020 20:44:34
User entered 'None (1)'	System	22 Sep 2020 20:44:34

FDA-CBER-2022-1614-0869913

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:57:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-22T15:44:27', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '796cb90f-1e60-4cf5-bb5c-c69149f639dd'	System	22 Sep 2020 20:44:34
User entered 'No (N)'	System	22 Sep 2020 20:44:34

FDA-CBER-2022-1614-0869914

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:57:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-22T15:44:28', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '796cb90f-1e60-4cf5-bb5c-c69149f639dd'	System	22 Sep 2020 20:44:34
User entered 'No (N)'	System	22 Sep 2020 20:44:34

FDA-CBER-2022-1614-0869915

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:57:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-22T15:44:30', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '796cb90f-1e60-4cf5-bb5c-c69149f639dd'	System	22 Sep 2020 20:44:34
User entered 'None (1)'	System	22 Sep 2020 20:44:34

FDA-CBER-2022-1614-0869916

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-22T15:44:32', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '796cb90f-1e60-4cf5-bb5c-c69149f639dd'	System	22 Sep 2020 20:44:34
User entered '22 Sep 2020 15:44'	System	22 Sep 2020 20:44:34

FDA-CBER-2022-1614-0869917

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869918

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869919

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 3'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869920

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:57:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-23T23:59:25', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '8406f902-5aa6-4dbf-9c5e-774fdb3c3fba'	System	24 Sep 2020 04:59:36
User entered 'None (1)'	System	24 Sep 2020 04:59:36

FDA-CBER-2022-1614-0869921

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:57:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-23T23:59:27', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '8406f902-5aa6-4dbf-9c5e-774fdb3c3fba'	System	24 Sep 2020 04:59:36
User entered 'No (N)'	System	24 Sep 2020 04:59:36

FDA-CBER-2022-1614-0869922

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:57:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-23T23:59:29', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '8406f902-5aa6-4dbf-9c5e-774fdb3c3fba'	System	24 Sep 2020 04:59:36
User entered 'No (N)'	System	24 Sep 2020 04:59:36

FDA-CBER-2022-1614-0869923

US3312095

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:57:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-23T23:59:31', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '8406f902-5aa6-4dbf-9c5e-774fdb3c3fba'	System	24 Sep 2020 04:59:36
User entered 'None (1)'	System	24 Sep 2020 04:59:36

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-23T23:59:33', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '8406f902-5aa6-4dbf-9c5e-774fdb3c3fba'	System	24 Sep 2020 04:59:36
User entered '23 Sep 2020 23:59'	System	24 Sep 2020 04:59:36

FDA-CBER-2022-1614-0869925

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869926

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

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US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 4'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869928

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:57:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T06:58:11', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '6d4dff02-f466-4e23-8e43-727199bed0e0'	System	25 Sep 2020 11:58:20
User entered 'None (1)'	System	25 Sep 2020 11:58:20

FDA-CBER-2022-1614-0869929

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:57:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T06:58:13', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '6d4dff02-f466-4e23-8e43-727199bed0e0'	System	25 Sep 2020 11:58:20
User entered 'No (N)'	System	25 Sep 2020 11:58:20

FDA-CBER-2022-1614-0869930

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:57:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T06:58:14', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '6d4dff02-f466-4e23-8e43-727199bed0e0'	System	25 Sep 2020 11:58:20
User entered 'No (N)'	System	25 Sep 2020 11:58:20

FDA-CBER-2022-1614-0869931

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:57:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T06:58:16', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '6d4dff02-f466-4e23-8e43-727199bed0e0'	System	25 Sep 2020 11:58:20
User entered 'None (1)'	System	25 Sep 2020 11:58:20

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US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T06:58:18', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '6d4dff02-f466-4e23-8e43-727199bed0e0'	System	25 Sep 2020 11:58:20
User entered '25 Sep 2020 06:58'	System	25 Sep 2020 11:58:20

FDA-CBER-2022-1614-0869933

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869934

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869935

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 5'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869936

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:57:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T23:59:25', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '5c6c863f-fa77-49af-839a-eecb22dbc131'	System	26 Sep 2020 04:59:38
User entered 'None (1)'	System	26 Sep 2020 04:59:38

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:57:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T23:59:27', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '5c6c863f-fa77-49af-839a-eecb22dbc131'	System	26 Sep 2020 04:59:38
User entered 'No (N)'	System	26 Sep 2020 04:59:38

FDA-CBER-2022-1614-0869938

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:57:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T23:59:28', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '5c6c863f-fa77-49af-839a-eecb22dbc131'	System	26 Sep 2020 04:59:38
User entered 'No (N)'	System	26 Sep 2020 04:59:38

FDA-CBER-2022-1614-0869939

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:57:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T23:59:29', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '5c6c863f-fa77-49af-839a-eecb22dbc131'	System	26 Sep 2020 04:59:38
User entered 'None (1)'	System	26 Sep 2020 04:59:38

FDA-CBER-2022-1614-0869940

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T23:59:31', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '5c6c863f-fa77-49af-839a-eecb22dbc131'	System	26 Sep 2020 04:59:38
User entered '25 Sep 2020 23:59'	System	26 Sep 2020 04:59:38

FDA-CBER-2022-1614-0869941

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869942

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869943

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 6'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869944

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:57:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T09:41:33', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '794be6f2-536d-4acb-bbf8-c1e89b5ee1d9'	System	27 Sep 2020 14:41:42
User entered 'None (1)'	System	27 Sep 2020 14:41:42

FDA-CBER-2022-1614-0869945

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:57:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T09:41:35', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '794be6f2-536d-4acb-bbf8-c1e89b5ee1d9'	System	27 Sep 2020 14:41:42
User entered 'No (N)'	System	27 Sep 2020 14:41:42

FDA-CBER-2022-1614-0869946

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:57:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T09:41:37', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '794be6f2-536d-4acb-bbf8-c1e89b5ee1d9'	System	27 Sep 2020 14:41:42
User entered 'No (N)'	System	27 Sep 2020 14:41:42

FDA-CBER-2022-1614-0869947

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:57:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T09:41:39', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '794be6f2-536d-4acb-bbf8-c1e89b5ee1d9'	System	27 Sep 2020 14:41:42
User entered 'None (1)'	System	27 Sep 2020 14:41:42

FDA-CBER-2022-1614-0869948

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T09:41:40', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '794be6f2-536d-4acb-bbf8-c1e89b5ee1d9'	System	27 Sep 2020 14:41:42
User entered '27 Sep 2020 09:41'	System	27 Sep 2020 14:41:42

FDA-CBER-2022-1614-0869949

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869950

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869951

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 7'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869952

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:57:13
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T23:59:20', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '77ac06b7-5b3b-4291-91bf-e4fe90be1fba'	System	28 Sep 2020 04:59:34
User entered 'None (1)'	System	28 Sep 2020 04:59:34

FDA-CBER-2022-1614-0869953

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:57:13
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T23:59:21', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '77ac06b7-5b3b-4291-91bf-e4fe90be1fba'	System	28 Sep 2020 04:59:34
User entered 'No (N)'	System	28 Sep 2020 04:59:34

FDA-CBER-2022-1614-0869954

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:57:13
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T23:59:23', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '77ac06b7-5b3b-4291-91bf-e4fe90be1fba'	System	28 Sep 2020 04:59:34
User entered 'No (N)'	System	28 Sep 2020 04:59:34

FDA-CBER-2022-1614-0869955

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:57:13
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T23:59:25', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '77ac06b7-5b3b-4291-91bf-e4fe90be1fba'	System	28 Sep 2020 04:59:34
User entered 'None (1)'	System	28 Sep 2020 04:59:34

FDA-CBER-2022-1614-0869956

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:57:13
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T23:59:28', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '77ac06b7-5b3b-4291-91bf-e4fe90be1fba'	System	28 Sep 2020 04:59:34
User entered '27 Sep 2020 23:59'	System	28 Sep 2020 04:59:34

FDA-CBER-2022-1614-0869957

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869958

US3312095
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869959

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869960

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T10:00:19', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '7af7aa77-a0fe-4e05-ae9e-2c7c9de174cd'	System	21 Sep 2020 15:00:37
User entered 'None (0)'	System	21 Sep 2020 15:00:37

FDA-CBER-2022-1614-0869961

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T10:00:21', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '7af7aa77-a0fe-4e05-ae9e-2c7c9de174cd'	System	21 Sep 2020 15:00:37
User entered 'None (0)'	System	21 Sep 2020 15:00:37

FDA-CBER-2022-1614-0869962

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T10:00:22', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '7af7aa77-a0fe-4e05-ae9e-2c7c9de174cd'	System	21 Sep 2020 15:00:37
User entered 'None (0)'	System	21 Sep 2020 15:00:37

FDA-CBER-2022-1614-0869963

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T10:00:23', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '7af7aa77-a0fe-4e05-ae9e-2c7c9de174cd'	System	21 Sep 2020 15:00:37
User entered 'None (0)'	System	21 Sep 2020 15:00:37

FDA-CBER-2022-1614-0869964

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T10:00:25', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '7af7aa77-a0fe-4e05-ae9e-2c7c9de174cd'	System	21 Sep 2020 15:00:37
User entered 'None (0)'	System	21 Sep 2020 15:00:37

FDA-CBER-2022-1614-0869965

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T10:00:26', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '7af7aa77-a0fe-4e05-ae9e-2c7c9de174cd'	System	21 Sep 2020 15:00:37
User entered 'None (0)'	System	21 Sep 2020 15:00:37

FDA-CBER-2022-1614-0869966

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T10:00:30', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '7af7aa77-a0fe-4e05-ae9e-2c7c9de174cd'	System	21 Sep 2020 15:00:37
User entered 'No (N)'	System	21 Sep 2020 15:00:37

FDA-CBER-2022-1614-0869967

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T10:00:32', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '7af7aa77-a0fe-4e05-ae9e-2c7c9de174cd'	System	21 Sep 2020 15:00:37
User entered '21 Sep 2020 10:00'	System	21 Sep 2020 15:00:37

FDA-CBER-2022-1614-0869968

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '21 Sep 2020 09:45'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869969

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '21 Sep 2020 12:15'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869970

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869971

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T21:37:39', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c2948d62-0a0a-4e45-858c-ff624501d0a9'	System	22 Sep 2020 02:37:59
User entered 'None (0)'	System	22 Sep 2020 02:37:59

FDA-CBER-2022-1614-0869972

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T21:37:40', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c2948d62-0a0a-4e45-858c-ff624501d0a9'	System	22 Sep 2020 02:37:59
User entered 'None (0)'	System	22 Sep 2020 02:37:59

FDA-CBER-2022-1614-0869973

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T21:37:41', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c2948d62-0a0a-4e45-858c-ff624501d0a9'	System	22 Sep 2020 02:37:59
User entered 'None (0)'	System	22 Sep 2020 02:37:59

FDA-CBER-2022-1614-0869974

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T21:37:43', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c2948d62-0a0a-4e45-858c-ff624501d0a9'	System	22 Sep 2020 02:37:59
User entered 'None (0)'	System	22 Sep 2020 02:37:59

FDA-CBER-2022-1614-0869975

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T21:37:45', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c2948d62-0a0a-4e45-858c-ff624501d0a9'	System	22 Sep 2020 02:37:59
User entered 'None (0)'	System	22 Sep 2020 02:37:59

FDA-CBER-2022-1614-0869976

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T21:37:46', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c2948d62-0a0a-4e45-858c-ff624501d0a9'	System	22 Sep 2020 02:37:59
User entered 'None (0)'	System	22 Sep 2020 02:37:59

FDA-CBER-2022-1614-0869977

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T21:37:55', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c2948d62-0a0a-4e45-858c-ff624501d0a9'	System	22 Sep 2020 02:37:59
User entered 'Yes (Y)'	System	22 Sep 2020 02:37:59

FDA-CBER-2022-1614-0869978

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-21T21:37:57', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c2948d62-0a0a-4e45-858c-ff624501d0a9'	System	22 Sep 2020 02:37:59
User entered '21 Sep 2020 21:37'	System	22 Sep 2020 02:37:59

FDA-CBER-2022-1614-0869979

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '21 Sep 2020 13:10'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869980

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869981

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 2'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869982

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-22T15:44:34', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd2beac96-f802-4246-8c4a-31dac20bcb85'	System	22 Sep 2020 20:44:44
User entered 'None (0)'	System	22 Sep 2020 20:44:44

FDA-CBER-2022-1614-0869983

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-22T15:44:35', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd2beac96-f802-4246-8c4a-31dac20bcb85'	System	22 Sep 2020 20:44:44
User entered 'None (0)'	System	22 Sep 2020 20:44:44

FDA-CBER-2022-1614-0869984

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-22T15:44:36', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd2beac96-f802-4246-8c4a-31dac20bcb85'	System	22 Sep 2020 20:44:44
User entered 'None (0)'	System	22 Sep 2020 20:44:44

FDA-CBER-2022-1614-0869985

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-22T15:44:37', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd2beac96-f802-4246-8c4a-31dac20bcb85'	System	22 Sep 2020 20:44:44
User entered 'None (0)'	System	22 Sep 2020 20:44:44

FDA-CBER-2022-1614-0869986

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-22T15:44:38', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd2beac96-f802-4246-8c4a-31dac20bcb85'	System	22 Sep 2020 20:44:44
User entered 'None (0)'	System	22 Sep 2020 20:44:44

FDA-CBER-2022-1614-0869987

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-22T15:44:39', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd2beac96-f802-4246-8c4a-31dac20bcb85'	System	22 Sep 2020 20:44:44
User entered 'None (0)'	System	22 Sep 2020 20:44:44

FDA-CBER-2022-1614-0869988

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-22T15:44:40', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd2beac96-f802-4246-8c4a-31dac20bcb85'	System	22 Sep 2020 20:44:44
User entered 'No (N)'	System	22 Sep 2020 20:44:44

FDA-CBER-2022-1614-0869989

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-22T15:44:41', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd2beac96-f802-4246-8c4a-31dac20bcb85'	System	22 Sep 2020 20:44:44
User entered '22 Sep 2020 15:44'	System	22 Sep 2020 20:44:44

FDA-CBER-2022-1614-0869990

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869991

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869992

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 3'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0869993

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-23T23:59:36', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '03545a62-8e37-4cef-aa8d-d3c159690dce'	System	24 Sep 2020 04:59:50
User entered 'None (0)'	System	24 Sep 2020 04:59:50

FDA-CBER-2022-1614-0869994

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-23T23:59:37', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '03545a62-8e37-4cef-aa8d-d3c159690dce'	System	24 Sep 2020 04:59:50
User entered 'None (0)'	System	24 Sep 2020 04:59:50

FDA-CBER-2022-1614-0869995

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-23T23:59:39', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '03545a62-8e37-4cef-aa8d-d3c159690dce'	System	24 Sep 2020 04:59:50
User entered 'None (0)'	System	24 Sep 2020 04:59:50

FDA-CBER-2022-1614-0869996

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-23T23:59:40', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '03545a62-8e37-4cef-aa8d-d3c159690dce'	System	24 Sep 2020 04:59:50
User entered 'None (0)'	System	24 Sep 2020 04:59:50

FDA-CBER-2022-1614-0869997

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-23T23:59:41', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '03545a62-8e37-4cef-aa8d-d3c159690dce'	System	24 Sep 2020 04:59:50
User entered 'None (0)'	System	24 Sep 2020 04:59:50

FDA-CBER-2022-1614-0869998

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-23T23:59:43', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '03545a62-8e37-4cef-aa8d-d3c159690dce'	System	24 Sep 2020 04:59:50
User entered 'None (0)'	System	24 Sep 2020 04:59:50

FDA-CBER-2022-1614-0869999

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-23T23:59:45', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '03545a62-8e37-4cef-aa8d-d3c159690dce'	System	24 Sep 2020 04:59:50
User entered 'No (N)'	System	24 Sep 2020 04:59:50

FDA-CBER-2022-1614-0870000

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-23T23:59:47', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '03545a62-8e37-4cef-aa8d-d3c159690dce'	System	24 Sep 2020 04:59:50
User entered '23 Sep 2020 23:59'	System	24 Sep 2020 04:59:50

FDA-CBER-2022-1614-0870001

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0870002

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0870003

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 4'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0870004

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T06:58:20', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c47d65d9-ed0c-428b-85b9-a1d27a40a47f'	System	25 Sep 2020 11:58:35
User entered 'None (0)'	System	25 Sep 2020 11:58:35

FDA-CBER-2022-1614-0870005

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T06:58:22', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c47d65d9-ed0c-428b-85b9-a1d27a40a47f'	System	25 Sep 2020 11:58:35
User entered 'None (0)'	System	25 Sep 2020 11:58:35

FDA-CBER-2022-1614-0870006

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T06:58:23', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c47d65d9-ed0c-428b-85b9-a1d27a40a47f'	System	25 Sep 2020 11:58:35
User entered 'None (0)'	System	25 Sep 2020 11:58:35

FDA-CBER-2022-1614-0870007

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T06:58:24', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c47d65d9-ed0c-428b-85b9-a1d27a40a47f'	System	25 Sep 2020 11:58:35
User entered 'None (0)'	System	25 Sep 2020 11:58:35

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T06:58:25', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c47d65d9-ed0c-428b-85b9-a1d27a40a47f'	System	25 Sep 2020 11:58:35
User entered 'None (0)'	System	25 Sep 2020 11:58:35

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T06:58:26', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c47d65d9-ed0c-428b-85b9-a1d27a40a47f'	System	25 Sep 2020 11:58:35
User entered 'None (0)'	System	25 Sep 2020 11:58:35

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T06:58:28', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c47d65d9-ed0c-428b-85b9-a1d27a40a47f'	System	25 Sep 2020 11:58:35
User entered 'No (N)'	System	25 Sep 2020 11:58:35

FDA-CBER-2022-1614-0870011

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T06:58:30', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c47d65d9-ed0c-428b-85b9-a1d27a40a47f'	System	25 Sep 2020 11:58:35
User entered '25 Sep 2020 06:58'	System	25 Sep 2020 11:58:35

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0870013

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0870014

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 5'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0870015

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T23:59:34', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '10540505-92d4-4d83-a4a3-e1f0e45390d0'	System	26 Sep 2020 04:59:45
User entered 'None (0)'	System	26 Sep 2020 04:59:45

FDA-CBER-2022-1614-0870016

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T23:59:35', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '10540505-92d4-4d83-a4a3-e1f0e45390d0'	System	26 Sep 2020 04:59:45
User entered 'None (0)'	System	26 Sep 2020 04:59:45

FDA-CBER-2022-1614-0870017

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T23:59:36', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '10540505-92d4-4d83-a4a3-e1f0e45390d0'	System	26 Sep 2020 04:59:45
User entered 'None (0)'	System	26 Sep 2020 04:59:45

FDA-CBER-2022-1614-0870018

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T23:59:37', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '10540505-92d4-4d83-a4a3-e1f0e45390d0'	System	26 Sep 2020 04:59:45
User entered 'None (0)'	System	26 Sep 2020 04:59:45

FDA-CBER-2022-1614-0870019

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T23:59:38', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '10540505-92d4-4d83-a4a3-e1f0e45390d0'	System	26 Sep 2020 04:59:45
User entered 'None (0)'	System	26 Sep 2020 04:59:45

FDA-CBER-2022-1614-0870020

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T23:59:39', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '10540505-92d4-4d83-a4a3-e1f0e45390d0'	System	26 Sep 2020 04:59:45
User entered 'None (0)'	System	26 Sep 2020 04:59:45

FDA-CBER-2022-1614-0870021

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T23:59:41', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '10540505-92d4-4d83-a4a3-e1f0e45390d0'	System	26 Sep 2020 04:59:45
User entered 'No (N)'	System	26 Sep 2020 04:59:45

FDA-CBER-2022-1614-0870022

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-25T23:59:42', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '10540505-92d4-4d83-a4a3-e1f0e45390d0'	System	26 Sep 2020 04:59:45
User entered '25 Sep 2020 23:59'	System	26 Sep 2020 04:59:45

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0870024

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0870025

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 6'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0870026

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T09:41:43', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'fd498a0f-159e-461f-968b-6649263a71cb'	System	27 Sep 2020 14:41:57
User entered 'None (0)'	System	27 Sep 2020 14:41:57

FDA-CBER-2022-1614-0870027

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T09:41:44', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'fd498a0f-159e-461f-968b-6649263a71cb'	System	27 Sep 2020 14:41:57
User entered 'None (0)'	System	27 Sep 2020 14:41:57

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T09:41:45', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'fd498a0f-159e-461f-968b-6649263a71cb'	System	27 Sep 2020 14:41:57
User entered 'None (0)'	System	27 Sep 2020 14:41:57

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T09:41:47', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'fd498a0f-159e-461f-968b-6649263a71cb'	System	27 Sep 2020 14:41:57
User entered 'None (0)'	System	27 Sep 2020 14:41:57

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T09:41:48', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'fd498a0f-159e-461f-968b-6649263a71cb'	System	27 Sep 2020 14:41:57
User entered 'None (0)'	System	27 Sep 2020 14:41:57

FDA-CBER-2022-1614-0870031

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T09:41:49', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'fd498a0f-159e-461f-968b-6649263a71cb'	System	27 Sep 2020 14:41:57
User entered 'None (0)'	System	27 Sep 2020 14:41:57

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T09:41:50', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'fd498a0f-159e-461f-968b-6649263a71cb'	System	27 Sep 2020 14:41:57
User entered 'No (N)'	System	27 Sep 2020 14:41:57

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T09:41:52', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'fd498a0f-159e-461f-968b-6649263a71cb'	System	27 Sep 2020 14:41:57
User entered '27 Sep 2020 09:41'	System	27 Sep 2020 14:41:57

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0870035

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0870036

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	21 Sep 2020 14:29:29
User entered 'Day 7'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0870037

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T23:59:31', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'da53bf3d-816f-4313-8dcc-357c8a358780'	System	28 Sep 2020 04:59:45
User entered 'None (0)'	System	28 Sep 2020 04:59:45

FDA-CBER-2022-1614-0870038

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T23:59:32', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'da53bf3d-816f-4313-8dcc-357c8a358780'	System	28 Sep 2020 04:59:45
User entered 'None (0)'	System	28 Sep 2020 04:59:45

FDA-CBER-2022-1614-0870039

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T23:59:34', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'da53bf3d-816f-4313-8dcc-357c8a358780'	System	28 Sep 2020 04:59:45
User entered 'None (0)'	System	28 Sep 2020 04:59:45

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T23:59:35', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'da53bf3d-816f-4313-8dcc-357c8a358780'	System	28 Sep 2020 04:59:45
User entered 'None (0)'	System	28 Sep 2020 04:59:45

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T23:59:36', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'da53bf3d-816f-4313-8dcc-357c8a358780'	System	28 Sep 2020 04:59:45
User entered 'None (0)'	System	28 Sep 2020 04:59:45

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T23:59:38', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'da53bf3d-816f-4313-8dcc-357c8a358780'	System	28 Sep 2020 04:59:45
User entered 'None (0)'	System	28 Sep 2020 04:59:45

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T23:59:39', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'da53bf3d-816f-4313-8dcc-357c8a358780'	System	28 Sep 2020 04:59:45
User entered 'No (N)'	System	28 Sep 2020 04:59:45

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-09-27T23:59:41', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'da53bf3d-816f-4313-8dcc-357c8a358780'	System	28 Sep 2020 04:59:45
User entered '27 Sep 2020 23:59'	System	28 Sep 2020 04:59:45

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0870046

US3312095
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:57:13
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 14:29:29

FDA-CBER-2022-1614-0870047

US3312095
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:27
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	01 Oct 2020 00:18:11

US3312095
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:27
User entered '28 Sep 2020'	Monica Atwood (b) (4) (b) (4)	01 Oct 2020 00:18:11

US3312095
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:27
User entered 'Contact Made (CONTACT MADE)'	Monica Atwood (b) (4) (b) (4)	01 Oct 2020 00:18:11

US3312095
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:27
User entered empty.	Monica Atwood (b) (4) (b) (4)	01 Oct 2020 00:18:11

FDA-CBER-2022-1614-0870051

US3312095
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:36
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	01 Oct 2020 00:18:17

US3312095
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered '1'	System	01 Oct 2020 00:18:17

FDA-CBER-2022-1614-0870053

US3312095
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:29:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 15:54:18

US3312095
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:29:12
User entered '05 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 15:54:18

US3312095
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Oct 2020 15:54:18

US3312095
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:12
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 15:54:18

FDA-CBER-2022-1614-0870057

US3312095
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 15:54:21

US3312095
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered '1'	System	20 Oct 2020 15:54:21

FDA-CBER-2022-1614-0870059

US3312095
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 15:54:36

US3312095
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:30:00
User entered '12 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 15:54:36

US3312095
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Oct 2020 15:54:36

US3312095
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:00
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 15:54:36

FDA-CBER-2022-1614-0870063

US3312095
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:48:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 15:54:39

US3312095
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered '1'	System	20 Oct 2020 15:54:39

FDA-CBER-2022-1614-0870065

US3312095
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:46
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:32:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 18:47:03

FDA-CBER-2022-1614-0870066

US3312095
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:46
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:32:37
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21OCT2020 is reported under Visit 3 Day 57 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 00:18:06
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21OCT2020 is reported under Visit 3 Day 57 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. ' answered with 'updated' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Nov 2020 15:23:50
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21OCT2020 is reported under Visit 3 Day 57 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:47:57
User entered '21 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 18:47:03

US3312095
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
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 00:30:46
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:32:37
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	27 Oct 2020 18:47:03

US3312095
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:46
User entered 'VISIT3'	System	27 Oct 2020 18:47:03

FDA-CBER-2022-1614-0870069

US3312095
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:33:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 18:47:29

FDA-CBER-2022-1614-0870070

US3312095
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:46
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:33:03
User entered '21 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 18:47:29

US3312095
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:33:03
User entered '13:02'	(b) (4), (b) (6)	27 Oct 2020 18:47:29

FDA-CBER-2022-1614-0870072

US3312095
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:46
User entered '21 Oct 2020 13:02'	System	27 Oct 2020 18:47:29

FDA-CBER-2022-1614-0870073

US3312095
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:46
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:33:03
User entered '98.1' F	(b) (4), (b) (6)	27 Oct 2020 18:47:29

US3312095
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:33:03
User entered 'Oral (Oral)'	(b) (4), (b) (6)	27 Oct 2020 18:47:29

FDA-CBER-2022-1614-0870075

US3312095
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:46
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:33:03
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 18:47:29

US3312095
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:33:03
User entered '66'	(b) (4), (b) (6)	27 Oct 2020 18:47:29

FDA-CBER-2022-1614-0870077

US3312095
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:46
User entered 'bpm'	System	27 Oct 2020 18:47:29

FDA-CBER-2022-1614-0870078

US3312095
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:46
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:33:03
User entered '14'	(b) (4), (b) (6)	27 Oct 2020 18:47:29

FDA-CBER-2022-1614-0870079

US3312095
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:46
User entered 'breaths/min'	System	27 Oct 2020 18:47:29

FDA-CBER-2022-1614-0870080

US3312095
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:46
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:33:03
User entered '135'	(b) (4), (b) (6)	27 Oct 2020 18:47:29

FDA-CBER-2022-1614-0870081

US3312095
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:46
User entered 'mmHg'	System	27 Oct 2020 18:47:29

FDA-CBER-2022-1614-0870082

US3312095
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:46
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:33:03
User entered '79'	(b) (4), (b) (6)	27 Oct 2020 18:47:29

FDA-CBER-2022-1614-0870083

US3312095
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:46
User entered 'mmHg'	System	27 Oct 2020 18:47:29

FDA-CBER-2022-1614-0870084

US3312095
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:46

FDA-CBER-2022-1614-0870085

US3312095
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:46

FDA-CBER-2022-1614-0870086

US3312095
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:57:13
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:33:10
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 16:34:32

FDA-CBER-2022-1614-0870087

US3312095
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:57:13
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:33:10
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 16:34:32

US3312095
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:57:13
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:33:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 16:34:42

US3312095
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:57:13
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:33:16
User entered '21 Oct 2020'	(b) (4), (b) (6)	17 Nov 2020 16:34:42

US3312095
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:57:13
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:33:16
User entered '13:16'	(b) (4), (b) (6)	17 Nov 2020 16:34:42

US3312095
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:57:13
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered '21 Oct 2020 13:16'	System	17 Nov 2020 16:34:42

FDA-CBER-2022-1614-0870092

US3312095
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:48:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:33:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 16:35:22

US3312095
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered '1'	System	17 Nov 2020 16:35:22

FDA-CBER-2022-1614-0870094

US3312095
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 64'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0870095

US3312095

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-10-17T00:01:50', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '95e7b969-c26e-49d3-8a81-47dd431d309e'	System	17 Oct 2020 05:01:58
User entered 'No (N)'	System	17 Oct 2020 05:01:58

US3312095

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-10-17T00:01:52', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '95e7b969-c26e-49d3-8a81-47dd431d309e'	System	17 Oct 2020 05:01:58
User entered 'No (N)'	System	17 Oct 2020 05:01:58

US3312095
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-10-17T00:01:55', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '95e7b969-c26e-49d3-8a81-47dd431d309e'	System	17 Oct 2020 05:01:58
User entered '17 Oct 2020 00:01:55'	System	17 Oct 2020 05:01:58

US3312095
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0870099

US3312095
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0870100

US3312095
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 71'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0870101

US3312095

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-10-24T05:55:28', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '52593ead-ed5c-4b84-8ee9-a6fbc98b8386'	System	24 Oct 2020 10:55:35
User entered 'No (N)'	System	24 Oct 2020 10:55:35

US3312095

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-10-24T05:55:29', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '52593ead-ed5c-4b84-8ee9-a6fbc98b8386'	System	24 Oct 2020 10:55:35
User entered 'No (N)'	System	24 Oct 2020 10:55:35

US3312095
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-10-24T05:55:32', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '52593ead-ed5c-4b84-8ee9-a6fbc98b8386'	System	24 Oct 2020 10:55:35
User entered '24 Oct 2020 05:55:32'	System	24 Oct 2020 10:55:35

US3312095
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0870105

US3312095
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0870106

US3312095
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 78'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0870107

US3312095

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-10-31T00:01:10', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c77d12df-e0b4-4c12-b4f9-45c90b20459a'	System	31 Oct 2020 06:01:27
User entered 'No (N)'	System	31 Oct 2020 06:01:27

US3312095

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-10-31T00:01:21', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c77d12df-e0b4-4c12-b4f9-45c90b20459a'	System	31 Oct 2020 06:01:27
User entered 'No (N)'	System	31 Oct 2020 06:01:27

US3312095
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-10-31T00:01:23', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'c77d12df-e0b4-4c12-b4f9-45c90b20459a'	System	31 Oct 2020 06:01:27
User entered '31 Oct 2020 00:01:23'	System	31 Oct 2020 06:01:27

US3312095
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0870111

US3312095
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0870112

US3312095
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered 'Day 92'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0870113

US3312095

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-11-14T00:01:38', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'dcaaa9d4-3229-4150-8c81-a55d37033827'	System	14 Nov 2020 06:01:59
User entered 'Yes (Y)'	System	14 Nov 2020 06:01:59

US3312095

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-11-14T00:01:46', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'dcaaa9d4-3229-4150-8c81-a55d37033827'	System	14 Nov 2020 06:01:59
User entered 'No (N)'	System	14 Nov 2020 06:01:59

US3312095

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-11-14T00:01:48', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'dcaaa9d4-3229-4150-8c81-a55d37033827'	System	14 Nov 2020 06:01:59
User entered 'No (N)'	System	14 Nov 2020 06:01:59

US3312095

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-11-14T00:01:51', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'dcaaa9d4-3229-4150-8c81-a55d37033827'	System	14 Nov 2020 06:01:59
User entered 'No (N)'	System	14 Nov 2020 06:01:59

US3312095
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-11-14T00:01:55', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'dcaaa9d4-3229-4150-8c81-a55d37033827'	System	14 Nov 2020 06:01:59
User entered '14 Nov 2020 00:01:55'	System	14 Nov 2020 06:01:59

US3312095
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0870119

US3312095
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:40:55
Data entry locked.	System	17 Aug 2020 15:39:39
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 15:39:39

FDA-CBER-2022-1614-0870120

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870121

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-11-21T06:40:38', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '65151ec1-26b1-4e49-bc2e-326646b9b15c'	System	21 Nov 2020 12:40:46
User entered 'No (N)'	System	21 Nov 2020 12:40:46

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-11-21T06:40:41', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '65151ec1-26b1-4e49-bc2e-326646b9b15c'	System	21 Nov 2020 12:40:46
User entered 'No (N)'	System	21 Nov 2020 12:40:46

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-11-21T06:40:43', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '65151ec1-26b1-4e49-bc2e-326646b9b15c'	System	21 Nov 2020 12:40:46
User entered '21 Nov 2020 06:40:43'	System	21 Nov 2020 12:40:46

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870125

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870126

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870127

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-11-25T01:44:17', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '1de084bf-fced-479c-880b-9e09169097ed'	System	25 Nov 2020 07:44:31
User entered 'Yes (Y)'	System	25 Nov 2020 07:44:31

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-11-25T01:44:20', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '1de084bf-fced-479c-880b-9e09169097ed'	System	25 Nov 2020 07:44:31
User entered 'No (N)'	System	25 Nov 2020 07:44:31

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-11-25T01:44:21', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '1de084bf-fced-479c-880b-9e09169097ed'	System	25 Nov 2020 07:44:31
User entered 'No (N)'	System	25 Nov 2020 07:44:31

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-11-25T01:44:23', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '1de084bf-fced-479c-880b-9e09169097ed'	System	25 Nov 2020 07:44:31
User entered 'No (N)'	System	25 Nov 2020 07:44:31

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-11-25T01:44:25', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '1de084bf-fced-479c-880b-9e09169097ed'	System	25 Nov 2020 07:44:31
User entered '25 Nov 2020 01:44:25'	System	25 Nov 2020 07:44:31

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870133

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870134

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870135

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-12-02T00:28:19', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '6f6958d9-c0f7-4d8d-91b8-4c100fed3416'	System	02 Dec 2020 06:28:42
User entered 'No (N)'	System	02 Dec 2020 06:28:42

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-12-02T00:28:35', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '6f6958d9-c0f7-4d8d-91b8-4c100fed3416'	System	02 Dec 2020 06:28:42
User entered 'No (N)'	System	02 Dec 2020 06:28:42

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-12-02T00:28:38', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '6f6958d9-c0f7-4d8d-91b8-4c100fed3416'	System	02 Dec 2020 06:28:42
User entered '02 Dec 2020 00:28:38'	System	02 Dec 2020 06:28:42

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870139

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870140

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870141

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-12-09T08:24:04', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'fa573b8f-e3f5-4c4c-8696-0860f8145d2e'	System	09 Dec 2020 14:24:20
User entered 'No (N)'	System	09 Dec 2020 14:24:20

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-12-09T08:24:12', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'fa573b8f-e3f5-4c4c-8696-0860f8145d2e'	System	09 Dec 2020 14:24:20
User entered 'No (N)'	System	09 Dec 2020 14:24:20

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-12-09T08:24:16', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'fa573b8f-e3f5-4c4c-8696-0860f8145d2e'	System	09 Dec 2020 14:24:20
User entered '09 Dec 2020 08:24:16'	System	09 Dec 2020 14:24:20

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870145

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870146

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870147

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-12-16T01:04:42', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'dd2605f6-3913-4081-8e07-792ee2b12100'	System	16 Dec 2020 07:04:50
User entered 'No (N)'	System	16 Dec 2020 07:04:50

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-12-16T01:04:45', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'dd2605f6-3913-4081-8e07-792ee2b12100'	System	16 Dec 2020 07:04:50
User entered 'No (N)'	System	16 Dec 2020 07:04:50

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-12-16T01:04:47', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'dd2605f6-3913-4081-8e07-792ee2b12100'	System	16 Dec 2020 07:04:50
User entered '16 Dec 2020 01:04:47'	System	16 Dec 2020 07:04:50

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870151

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870152

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870153

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-12-23T00:02:52', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '2adb3bd9-7db2-4e85-aee9-350b42e3c88a'	System	23 Dec 2020 06:03:01
User entered 'No (N)'	System	23 Dec 2020 06:03:01

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-12-23T00:02:54', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '2adb3bd9-7db2-4e85-aee9-350b42e3c88a'	System	23 Dec 2020 06:03:01
User entered 'No (N)'	System	23 Dec 2020 06:03:01

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-12-23T00:02:56', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '2adb3bd9-7db2-4e85-aee9-350b42e3c88a'	System	23 Dec 2020 06:03:01
User entered '23 Dec 2020 00:02:56'	System	23 Dec 2020 06:03:01

FDA-CBER-2022-1614-0870156

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870157

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870158

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870159

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-12-30T04:57:55', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '059f30ec-9108-45a0-9866-1eec9bbc08fe'	System	30 Dec 2020 10:58:06
User entered 'No (N)'	System	30 Dec 2020 10:58:06

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-12-30T04:57:58', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '059f30ec-9108-45a0-9866-1eec9bbc08fe'	System	30 Dec 2020 10:58:06
User entered 'No (N)'	System	30 Dec 2020 10:58:06

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2020-12-30T04:58:01', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '059f30ec-9108-45a0-9866-1eec9bbc08fe'	System	30 Dec 2020 10:58:06
User entered '30 Dec 2020 04:58:01'	System	30 Dec 2020 10:58:06

FDA-CBER-2022-1614-0870162

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870163

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870164

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870165

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-01-06T09:18:23', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '99641133-d284-4f97-9d33-f6e0f8127790'	System	06 Jan 2021 15:18:45
User entered 'No (N)'	System	06 Jan 2021 15:18:45

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-01-06T09:18:25', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '99641133-d284-4f97-9d33-f6e0f8127790'	System	06 Jan 2021 15:18:45
User entered 'No (N)'	System	06 Jan 2021 15:18:45

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-01-06T09:18:28', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '99641133-d284-4f97-9d33-f6e0f8127790'	System	06 Jan 2021 15:18:45
User entered '06 Jan 2021 09:18:28'	System	06 Jan 2021 15:18:45

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870169

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870170

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870171

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-01-13T09:09:51', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ffd78fd6-f501-4dee-a4d3-57cafcb5d32b'	System	13 Jan 2021 15:09:58
User entered 'No (N)'	System	13 Jan 2021 15:09:58

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-01-13T09:09:52', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ffd78fd6-f501-4dee-a4d3-57cafcb5d32b'	System	13 Jan 2021 15:09:58
User entered 'No (N)'	System	13 Jan 2021 15:09:58

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-01-13T09:09:54', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ffd78fd6-f501-4dee-a4d3-57cafcb5d32b'	System	13 Jan 2021 15:09:58
User entered '13 Jan 2021 09:09:54'	System	13 Jan 2021 15:09:58

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870175

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870176

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870177

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-01-20T03:58:38', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '083b8f2f-923b-438b-b814-a5a5139af801'	System	20 Jan 2021 09:58:47
User entered 'No (N)'	System	20 Jan 2021 09:58:47

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-01-20T03:58:39', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '083b8f2f-923b-438b-b814-a5a5139af801'	System	20 Jan 2021 09:58:47
User entered 'No (N)'	System	20 Jan 2021 09:58:47

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-01-20T03:58:41', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '083b8f2f-923b-438b-b814-a5a5139af801'	System	20 Jan 2021 09:58:47
User entered '20 Jan 2021 03:58:41'	System	20 Jan 2021 09:58:47

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870181

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870182

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870183

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-01-28T12:46:15', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ed7207c5-4e70-4d42-900f-863827a26dd3'	System	28 Jan 2021 18:46:19
User entered 'No (N)'	System	28 Jan 2021 18:46:19

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-01-28T12:46:16', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ed7207c5-4e70-4d42-900f-863827a26dd3'	System	28 Jan 2021 18:46:19
User entered 'No (N)'	System	28 Jan 2021 18:46:19

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-01-28T12:46:18', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'ed7207c5-4e70-4d42-900f-863827a26dd3'	System	28 Jan 2021 18:46:19
User entered '28 Jan 2021 12:46:18'	System	28 Jan 2021 18:46:19

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870187

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870188

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870189

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-02-03T00:02:06', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '896948f9-5132-4963-9e9b-91a89a489a1c'	System	03 Feb 2021 06:02:16
User entered 'No (N)'	System	03 Feb 2021 06:02:16

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-02-03T00:02:11', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '896948f9-5132-4963-9e9b-91a89a489a1c'	System	03 Feb 2021 06:02:16
User entered 'No (N)'	System	03 Feb 2021 06:02:16

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-02-03T00:02:14', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '896948f9-5132-4963-9e9b-91a89a489a1c'	System	03 Feb 2021 06:02:16
User entered '03 Feb 2021 00:02:14'	System	03 Feb 2021 06:02:16

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870193

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870194

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870195

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-02-10T00:42:53', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'f78035c8-64db-41df-82e8-0e309df5f425'	System	10 Feb 2021 06:43:03
User entered 'No (N)'	System	10 Feb 2021 06:43:03

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-02-10T00:42:56', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'f78035c8-64db-41df-82e8-0e309df5f425'	System	10 Feb 2021 06:43:03
User entered 'No (N)'	System	10 Feb 2021 06:43:03

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-02-10T00:42:58', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'f78035c8-64db-41df-82e8-0e309df5f425'	System	10 Feb 2021 06:43:03
User entered '10 Feb 2021 00:42:58'	System	10 Feb 2021 06:43:03

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870199

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870200

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870201

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-02-17T18:16:42', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '1df20dd0-e1c6-463c-8737-ea49f6d04c7b'	System	18 Feb 2021 00:17:07
User entered 'Yes (Y)'	System	18 Feb 2021 00:17:07

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-02-17T18:16:44', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '1df20dd0-e1c6-463c-8737-ea49f6d04c7b'	System	18 Feb 2021 00:17:07
User entered 'No (N)'	System	18 Feb 2021 00:17:07

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-02-17T18:16:47', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '1df20dd0-e1c6-463c-8737-ea49f6d04c7b'	System	18 Feb 2021 00:17:07
User entered 'No (N)'	System	18 Feb 2021 00:17:07

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-02-17T18:16:50', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '1df20dd0-e1c6-463c-8737-ea49f6d04c7b'	System	18 Feb 2021 00:17:07
User entered 'Yes (Y)'	System	18 Feb 2021 00:17:07

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Please 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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-02-17T18:16:54', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '1df20dd0-e1c6-463c-8737-ea49f6d04c7b'	System	18 Feb 2021 00:17:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Feb 2021 00:17:07

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-02-17T18:16:56', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '1df20dd0-e1c6-463c-8737-ea49f6d04c7b'	System	18 Feb 2021 00:17:07
User entered '17 Feb 2021 18:16:56'	System	18 Feb 2021 00:17:07

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870208

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870209

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870210

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-02-24T01:00:24', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'f073d36c-1193-4717-9ee3-f69272522c72'	System	24 Feb 2021 07:00:33
User entered 'No (N)'	System	24 Feb 2021 07:00:33

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-02-24T01:00:27', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'f073d36c-1193-4717-9ee3-f69272522c72'	System	24 Feb 2021 07:00:33
User entered 'No (N)'	System	24 Feb 2021 07:00:33

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-02-24T01:00:29', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'f073d36c-1193-4717-9ee3-f69272522c72'	System	24 Feb 2021 07:00:33
User entered '24 Feb 2021 01:00:29'	System	24 Feb 2021 07:00:33

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870214

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870215

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870216

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-03-04T09:20:04-06:00', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd18f18eb-c2c2-4fb8-b921-6d92e006a1e4'	System	04 Mar 2021 15:20:12
User entered 'No (N)'	System	04 Mar 2021 15:20:12

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-03-04T09:20:07-06:00', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd18f18eb-c2c2-4fb8-b921-6d92e006a1e4'	System	04 Mar 2021 15:20:12
User entered 'No (N)'	System	04 Mar 2021 15:20:12

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-03-04T09:20:09-06:00', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'd18f18eb-c2c2-4fb8-b921-6d92e006a1e4'	System	04 Mar 2021 15:20:12
User entered '04 Mar 2021 09:20:09'	System	04 Mar 2021 15:20:12

FDA-CBER-2022-1614-0870219

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870220

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870221

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870222

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-03-10T06:39:59-05:00', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '5cfe2414-e6ec-48f7-9172-a91dd01696d4'	System	10 Mar 2021 11:40:06
User entered 'No (N)'	System	10 Mar 2021 11:40:06

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-03-10T06:40:01-05:00', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '5cfe2414-e6ec-48f7-9172-a91dd01696d4'	System	10 Mar 2021 11:40:06
User entered 'No (N)'	System	10 Mar 2021 11:40:06

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-03-10T06:40:02-05:00', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: '5cfe2414-e6ec-48f7-9172-a91dd01696d4'	System	10 Mar 2021 11:40:06
User entered '10 Mar 2021 06:40:02'	System	10 Mar 2021 11:40:06

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870226

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870227

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870228

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-03-18T18:14:27-04:00', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'fb6d1e42-357a-4376-9d7c-f6bea88d0783'	System	18 Mar 2021 22:16:54
User entered 'No (N)'	System	18 Mar 2021 22:16:54

US3312095

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-03-18T18:14:28-04:00', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'fb6d1e42-357a-4376-9d7c-f6bea88d0783'	System	18 Mar 2021 22:16:54
User entered 'No (N)'	System	18 Mar 2021 22:16:54

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-03-18T18:14:30-04:00', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'fb6d1e42-357a-4376-9d7c-f6bea88d0783'	System	18 Mar 2021 22:16:54
User entered '18 Mar 2021 18:14:30'	System	18 Mar 2021 22:16:54

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870232

US3312095
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:57:13
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:01:08
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 09:01:08

FDA-CBER-2022-1614-0870233

US3312095

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:57:13

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)	30 Apr 2021 15:54:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-02-28T19:27:42', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'bed2001a-7e9d-4263-a3c7-bb9349bfc639'	System	01 Mar 2021 01:27:49
User entered 'No (N)'	System	01 Mar 2021 01:27:49

US3312095
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary (1)
Generated On: 09 Jun 2021 16:57:13
Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:54:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D685E80-3AEA-451C-BB85-A4423D2ACA40)', Time: '2021-02-28T19:27:45', User OID: 'PatientReportedOutcome (US3312095)', ODM File OID: 'bed2001a-7e9d-4263-a3c7-bb9349bfc639'	System	01 Mar 2021 01:27:49
User entered '28 Feb 2021 19:27:45'	System	01 Mar 2021 01:27:49

US3312095
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:34:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 16:36:55

US3312095
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:34:27
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 16:36:55

US3312095
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:34:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Nov 2020 16:36:55

US3312095
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:34:27
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 16:36:55

US3312095
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:34:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 16:37:14

US3312095
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:45
User entered '1'	System	17 Nov 2020 16:37:14

FDA-CBER-2022-1614-0870241

US3312095
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:12:02
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 18:44:32

US3312095
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:12:02
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 18:44:32

US3312095
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:12:02
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 18:44:32

FDA-CBER-2022-1614-0870244

US3312095
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:12:02
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'OCCURRED DURING CONVALESCENT PERIOD'	(b) (4), (b) (6)	22 Jan 2021 18:44:32

FDA-CBER-2022-1614-0870245

US3312095
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:12:07
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 18:44:36

FDA-CBER-2022-1614-0870246

US3312095
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:52
User entered '1'	System	22 Jan 2021 18:44:36

FDA-CBER-2022-1614-0870247

US3312095
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:11:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	26 Feb 2021 18:15:06

US3312095
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:11:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '19 Jan 2021'	Karol Moore (b) (4) (b) (4)	26 Feb 2021 18:15:06

US3312095
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:11:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	26 Feb 2021 18:15:06

US3312095
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:11:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	26 Feb 2021 18:15:06

FDA-CBER-2022-1614-0870251

US3312095
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:11:14
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	26 Feb 2021 18:15:10

US3312095
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:52
User entered '1'	System	26 Feb 2021 18:15:10

FDA-CBER-2022-1614-0870253

US3312095
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	26 Feb 2021 18:16:33

US3312095
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '15 Feb 2021'	Karol Moore (b) (4) (b) (4)	26 Feb 2021 18:16:33

US3312095
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Contact Not Made (CONTACT NOT MADE)'	Karol Moore (b) (4) (b) (4)	26 Feb 2021 18:16:33

US3312095
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:57:13
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'ATTEMPTS MADE ON 15FEB21, 16FEB21, AND 17FEB21. DEVIATION NOTED.'	Karol Moore (b) (4) (b) (4)	26 Feb 2021 18:16:33

FDA-CBER-2022-1614-0870257

US3312095
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:36
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	26 Feb 2021 18:16:39

FDA-CBER-2022-1614-0870258

US3312095
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:57:13
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:52
User entered '1'	System	26 Feb 2021 18:16:39

FDA-CBER-2022-1614-0870259

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 16:57:13
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:37:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '04 Dec 2020'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 22:59:49

FDA-CBER-2022-1614-0870260

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 16:57:13
Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:37:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '16:56'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 22:59:49

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 16:57:13
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
User entered '04 Dec 2020 16:56'	System	08 Dec 2020 22:59:49

FDA-CBER-2022-1614-0870262

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 16:57:13
Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:37:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Safety Call (Safety Call)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 22:59:49

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 16:57:13
Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:37:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 22:59:49

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Day 1 (Day 1)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

FDA-CBER-2022-1614-0870265

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '03 Dec 2020'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

FDA-CBER-2022-1614-0870266

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '0'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

FDA-CBER-2022-1614-0870267

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:37:03
User entered empty.	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User entered '%'	System	28 Dec 2020 19:37:03
User entered empty.	System	08 Dec 2020 23:12:20

FDA-CBER-2022-1614-0870269

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:37:03
User entered empty.	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

FDA-CBER-2022-1614-0870272

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

FDA-CBER-2022-1614-0870273

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

FDA-CBER-2022-1614-0870274

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

FDA-CBER-2022-1614-0870275

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

FDA-CBER-2022-1614-0870276

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

FDA-CBER-2022-1614-0870277

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

FDA-CBER-2022-1614-0870278

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

FDA-CBER-2022-1614-0870279

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

FDA-CBER-2022-1614-0870280

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

FDA-CBER-2022-1614-0870281

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

FDA-CBER-2022-1614-0870282

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

FDA-CBER-2022-1614-0870283

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

FDA-CBER-2022-1614-0870284

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

FDA-CBER-2022-1614-0870285

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 16:57:13
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:20

FDA-CBER-2022-1614-0870286

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Day 2 (Day 2)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

FDA-CBER-2022-1614-0870287

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '04 Dec 2020'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

FDA-CBER-2022-1614-0870288

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '0'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

FDA-CBER-2022-1614-0870289

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:37:03
User entered empty.	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User entered '%'	System	28 Dec 2020 19:37:03
User entered empty.	System	08 Dec 2020 23:12:51

FDA-CBER-2022-1614-0870291

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:37:03
User entered empty.	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

FDA-CBER-2022-1614-0870294

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

FDA-CBER-2022-1614-0870295

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

FDA-CBER-2022-1614-0870296

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

FDA-CBER-2022-1614-0870297

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

FDA-CBER-2022-1614-0870298

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

FDA-CBER-2022-1614-0870299

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

FDA-CBER-2022-1614-0870300

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

FDA-CBER-2022-1614-0870301

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

FDA-CBER-2022-1614-0870302

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

FDA-CBER-2022-1614-0870303

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

FDA-CBER-2022-1614-0870304

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

FDA-CBER-2022-1614-0870305

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

FDA-CBER-2022-1614-0870306

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

FDA-CBER-2022-1614-0870307

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 16:57:13
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:12:51

FDA-CBER-2022-1614-0870308

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Day 3 (Day 3)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

FDA-CBER-2022-1614-0870309

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '05 Dec 2020'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

FDA-CBER-2022-1614-0870310

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '0'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:37:03
User entered empty.	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User entered '%'	System	28 Dec 2020 19:37:03
User entered empty.	System	08 Dec 2020 23:13:18

FDA-CBER-2022-1614-0870313

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:37:03
User entered empty.	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

FDA-CBER-2022-1614-0870315

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

FDA-CBER-2022-1614-0870316

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

FDA-CBER-2022-1614-0870317

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

FDA-CBER-2022-1614-0870318

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

FDA-CBER-2022-1614-0870319

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

FDA-CBER-2022-1614-0870320

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

FDA-CBER-2022-1614-0870321

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

FDA-CBER-2022-1614-0870322

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

FDA-CBER-2022-1614-0870323

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

FDA-CBER-2022-1614-0870324

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

FDA-CBER-2022-1614-0870325

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

FDA-CBER-2022-1614-0870326

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

FDA-CBER-2022-1614-0870327

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

FDA-CBER-2022-1614-0870328

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

FDA-CBER-2022-1614-0870329

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 16:57:13
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:13:18

FDA-CBER-2022-1614-0870330

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Day 4 (Day 4)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

FDA-CBER-2022-1614-0870331

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '06 Dec 2020'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

FDA-CBER-2022-1614-0870332

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '0'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

FDA-CBER-2022-1614-0870333

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:37:03
User entered empty.	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User entered '%'	System	28 Dec 2020 19:37:03
User entered empty.	System	08 Dec 2020 23:14:03

FDA-CBER-2022-1614-0870335

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:37:03
User entered empty.	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

FDA-CBER-2022-1614-0870337

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

FDA-CBER-2022-1614-0870338

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

FDA-CBER-2022-1614-0870339

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

FDA-CBER-2022-1614-0870340

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

FDA-CBER-2022-1614-0870341

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

FDA-CBER-2022-1614-0870342

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

FDA-CBER-2022-1614-0870343

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

FDA-CBER-2022-1614-0870344

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

FDA-CBER-2022-1614-0870345

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

FDA-CBER-2022-1614-0870346

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

FDA-CBER-2022-1614-0870347

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

FDA-CBER-2022-1614-0870348

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

FDA-CBER-2022-1614-0870349

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

FDA-CBER-2022-1614-0870350

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

FDA-CBER-2022-1614-0870351

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 16:57:13
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:03

FDA-CBER-2022-1614-0870352

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Day 5 (Day 5)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870353

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '07 Dec 2020'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870354

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '0'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870356

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User entered '%'	System	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870357

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '98.6' F	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870358

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870359

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870360

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870361

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870362

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870363

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870364

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870365

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870366

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870367

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870368

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870369

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870370

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870371

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870372

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870373

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 16:57:13
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 23:14:50

FDA-CBER-2022-1614-0870374

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Day 6 (Day 6)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

FDA-CBER-2022-1614-0870375

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '08 Dec 2020'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

FDA-CBER-2022-1614-0870376

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '97'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User entered '%'	System	10 Dec 2020 19:46:25

FDA-CBER-2022-1614-0870379

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '98.8' F	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

FDA-CBER-2022-1614-0870380

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

FDA-CBER-2022-1614-0870381

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

FDA-CBER-2022-1614-0870382

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

FDA-CBER-2022-1614-0870383

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

FDA-CBER-2022-1614-0870384

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

FDA-CBER-2022-1614-0870385

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

FDA-CBER-2022-1614-0870386

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

FDA-CBER-2022-1614-0870387

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

FDA-CBER-2022-1614-0870388

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

FDA-CBER-2022-1614-0870389

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

FDA-CBER-2022-1614-0870393

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

FDA-CBER-2022-1614-0870394

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

FDA-CBER-2022-1614-0870395

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 16:57:13
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:25

FDA-CBER-2022-1614-0870396

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Day 7 (Day 7)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

FDA-CBER-2022-1614-0870397

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '09 Dec 2020'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

FDA-CBER-2022-1614-0870398

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

FDA-CBER-2022-1614-0870399

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '99'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User entered '%'	System	10 Dec 2020 19:46:52

FDA-CBER-2022-1614-0870401

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '98.6' F	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

FDA-CBER-2022-1614-0870402

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

FDA-CBER-2022-1614-0870403

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

FDA-CBER-2022-1614-0870404

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

FDA-CBER-2022-1614-0870405

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

FDA-CBER-2022-1614-0870406

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

FDA-CBER-2022-1614-0870407

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

FDA-CBER-2022-1614-0870408

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

FDA-CBER-2022-1614-0870409

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

FDA-CBER-2022-1614-0870410

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

FDA-CBER-2022-1614-0870412

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

FDA-CBER-2022-1614-0870413

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

FDA-CBER-2022-1614-0870414

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

FDA-CBER-2022-1614-0870415

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

FDA-CBER-2022-1614-0870416

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

FDA-CBER-2022-1614-0870417

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 16:57:13
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Dec 2020 19:46:52

FDA-CBER-2022-1614-0870418

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Day 8 (Day 8)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870419

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User closed query 'Per ETRTR, Please add additional lines to record symptoms. According to protocol participants will be monitored by study investigator for a 14 day period after diagnosis, or until symptoms resolved, whatever is later. According to COVID Diagnostic Test, pt was diagnosed with covid19 on 10 Dec 2020.' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 21:14:28
Query 'Per ETRTR, Please add additional lines to record symptoms. According to protocol participants will be monitored by study investigator for a 14 day period after diagnosis, or until symptoms resolved, whatever is later. According to COVID Diagnostic Test, pt was diagnosed with covid19 on 10 Dec 2020.' answered with 'ADDITIONAL LINES ADDED' (Site from CRA).	Karol Moore (b) (4) (b) (4)	07 Jan 2021 16:11:07
User opened query 'Per ETRTR, Please add additional lines to record symptoms. According to protocol participants will be monitored by study investigator for a 14 day period after diagnosis, or until symptoms resolved, whatever is later. According to COVID Diagnostic Test, pt was diagnosed with covid19 on 10 Dec 2020.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 02:21:52
User entered '10 Dec 2020'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '0'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870421

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '96'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870422

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User entered '%'	System	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870423

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '97.8' F	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870424

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870425

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870426

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870427

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870428

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870429

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870430

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870431

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870432

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870433

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870434

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870435

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870436

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870437

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870438

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870439

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 16:57:13
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:02:33

FDA-CBER-2022-1614-0870440

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Day 9 (Day 9)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870441

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '11 Dec 2020'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870442

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '0'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '98'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870444

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User entered '%'	System	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870445

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '98.7' F	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870446

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870447

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870448

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870449

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870450

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870451

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870452

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870453

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870454

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870455

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870456

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870457

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870458

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870459

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870460

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870461

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 16:57:13
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Dec 2020 21:57:42

FDA-CBER-2022-1614-0870462

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User closed query 'Per CDM: Per sponsor review, COVID-19 AE end date is recorded as 12 Dec 2020. However, symptom log for 12 Dec 2020 records symptoms on that day. Please review and update either end date or symptom log as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 06:27:45
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
Query 'Per CDM: Per sponsor review, COVID-19 AE end date is recorded as 12 Dec 2020. However, symptom log for 12 Dec 2020 records symptoms on that day. Please review and update either end date or symptom log as appropriate.' answered with 'CORRECT AS ENTERED. END DATE SHOULD BE RECORDED AS LAST DAY WITH SYMPTOMS PRESENT' (Site from DM).	Karol Moore (b) (4) (b) (4)	05 Apr 2021 18:19:44
User opened query 'Per CDM: Per sponsor review, COVID-19 AE end date is recorded as 12 Dec 2020. However, symptom log for 12 Dec 2020 records symptoms on that day. Please review and update either end date or symptom log as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 17:30:22
User entered 'Day 10 (Day 10)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

FDA-CBER-2022-1614-0870463

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '12 Dec 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:11:17
User entered '10 Dec 2020'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

FDA-CBER-2022-1614-0870465

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '98'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

FDA-CBER-2022-1614-0870466

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User entered '%'	System	14 Dec 2020 23:37:33

FDA-CBER-2022-1614-0870467

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '97.5' F reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:11:17
User entered '98.7' F	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

FDA-CBER-2022-1614-0870469

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

FDA-CBER-2022-1614-0870470

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

FDA-CBER-2022-1614-0870471

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

FDA-CBER-2022-1614-0870472

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

FDA-CBER-2022-1614-0870473

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

FDA-CBER-2022-1614-0870474

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

FDA-CBER-2022-1614-0870475

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

FDA-CBER-2022-1614-0870476

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

FDA-CBER-2022-1614-0870477

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

FDA-CBER-2022-1614-0870478

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

FDA-CBER-2022-1614-0870479

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

FDA-CBER-2022-1614-0870480

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

FDA-CBER-2022-1614-0870481

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

FDA-CBER-2022-1614-0870482

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

FDA-CBER-2022-1614-0870483

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 16:57:13
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:33

FDA-CBER-2022-1614-0870484

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:29
User entered 'Day 12 (Day 12)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '13 Dec 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:11:17
User entered '12 Dec 2020'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

FDA-CBER-2022-1614-0870487

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '97' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:11:17
User entered '98'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User entered '%'	System	14 Dec 2020 23:37:58

FDA-CBER-2022-1614-0870489

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '98.7' F reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:11:17
User entered '97.5' F	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

FDA-CBER-2022-1614-0870491

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

FDA-CBER-2022-1614-0870492

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

FDA-CBER-2022-1614-0870493

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

FDA-CBER-2022-1614-0870494

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

FDA-CBER-2022-1614-0870495

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

FDA-CBER-2022-1614-0870496

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

FDA-CBER-2022-1614-0870497

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

FDA-CBER-2022-1614-0870498

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

FDA-CBER-2022-1614-0870499

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

FDA-CBER-2022-1614-0870500

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

FDA-CBER-2022-1614-0870501

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

FDA-CBER-2022-1614-0870502

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

FDA-CBER-2022-1614-0870503

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

FDA-CBER-2022-1614-0870504

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

FDA-CBER-2022-1614-0870505

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 16:57:13
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:37:58

FDA-CBER-2022-1614-0870506

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Day 12 (Day 12)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

FDA-CBER-2022-1614-0870507

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '14 Dec 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:11:17
User entered '13 Dec 2020'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

FDA-CBER-2022-1614-0870509

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '95' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:11:17
User entered '97'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User entered '%'	System	14 Dec 2020 23:38:20

FDA-CBER-2022-1614-0870511

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '98.8' F reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:11:17
User entered '98.7' F	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

FDA-CBER-2022-1614-0870513

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

FDA-CBER-2022-1614-0870514

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

FDA-CBER-2022-1614-0870515

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

FDA-CBER-2022-1614-0870516

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

FDA-CBER-2022-1614-0870517

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

FDA-CBER-2022-1614-0870518

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

FDA-CBER-2022-1614-0870519

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

FDA-CBER-2022-1614-0870520

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

FDA-CBER-2022-1614-0870521

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

FDA-CBER-2022-1614-0870522

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

FDA-CBER-2022-1614-0870523

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

FDA-CBER-2022-1614-0870524

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

FDA-CBER-2022-1614-0870525

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

FDA-CBER-2022-1614-0870526

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

FDA-CBER-2022-1614-0870527

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (12)
Generated On: 09 Jun 2021 16:57:13
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	14 Dec 2020 23:38:20

FDA-CBER-2022-1614-0870528

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Day 13 (Day 13)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

FDA-CBER-2022-1614-0870529

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '15 Dec 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:11:17
User entered '14 Dec 2020'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '0'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

FDA-CBER-2022-1614-0870531

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '97' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:11:17
User entered '95'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User entered '%'	System	16 Dec 2020 19:06:35

FDA-CBER-2022-1614-0870533

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '98.5' F reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:11:17
User entered '98.8' F	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

FDA-CBER-2022-1614-0870535

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

FDA-CBER-2022-1614-0870536

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

FDA-CBER-2022-1614-0870537

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

FDA-CBER-2022-1614-0870538

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

FDA-CBER-2022-1614-0870539

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

FDA-CBER-2022-1614-0870540

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

FDA-CBER-2022-1614-0870541

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

FDA-CBER-2022-1614-0870542

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

FDA-CBER-2022-1614-0870543

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

FDA-CBER-2022-1614-0870544

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

FDA-CBER-2022-1614-0870545

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

FDA-CBER-2022-1614-0870546

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

FDA-CBER-2022-1614-0870547

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

FDA-CBER-2022-1614-0870548

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

FDA-CBER-2022-1614-0870549

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (13)
Generated On: 09 Jun 2021 16:57:13
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:06:35

FDA-CBER-2022-1614-0870550

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:17:25
User entered 'Day 15 (Day 15)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '16 Dec 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26
User entered '15 Dec 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:11:17
User entered '14 Dec 2020'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '0'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '98' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26
User entered '95'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User entered '%'	System	16 Dec 2020 19:07:38

FDA-CBER-2022-1614-0870555

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '98.5' F reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26
User entered '98.8' F	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

FDA-CBER-2022-1614-0870557

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

FDA-CBER-2022-1614-0870558

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

FDA-CBER-2022-1614-0870559

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

FDA-CBER-2022-1614-0870560

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

FDA-CBER-2022-1614-0870561

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

FDA-CBER-2022-1614-0870563

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

FDA-CBER-2022-1614-0870564

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

FDA-CBER-2022-1614-0870565

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

FDA-CBER-2022-1614-0870566

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

FDA-CBER-2022-1614-0870567

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

FDA-CBER-2022-1614-0870568

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

FDA-CBER-2022-1614-0870569

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

FDA-CBER-2022-1614-0870570

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

FDA-CBER-2022-1614-0870571

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (14)
Generated On: 09 Jun 2021 16:57:13
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:07:38

FDA-CBER-2022-1614-0870572

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Day 15 (Day 15)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

FDA-CBER-2022-1614-0870573

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '17 Dec 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:17:18
User entered '15 Dec 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:11:17
User entered '14 Dec 2020'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '0'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '98' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:17:18
User entered '95'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User entered '%'	System	16 Dec 2020 19:08:11

FDA-CBER-2022-1614-0870577

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '98.6' F reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:17:18
User entered '98.8' F	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

FDA-CBER-2022-1614-0870579

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

FDA-CBER-2022-1614-0870580

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

FDA-CBER-2022-1614-0870581

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

FDA-CBER-2022-1614-0870582

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

FDA-CBER-2022-1614-0870583

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

FDA-CBER-2022-1614-0870584

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

FDA-CBER-2022-1614-0870585

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

FDA-CBER-2022-1614-0870586

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

FDA-CBER-2022-1614-0870587

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

FDA-CBER-2022-1614-0870588

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

FDA-CBER-2022-1614-0870589

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

FDA-CBER-2022-1614-0870590

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

FDA-CBER-2022-1614-0870591

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

FDA-CBER-2022-1614-0870592

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

FDA-CBER-2022-1614-0870593

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (15)
Generated On: 09 Jun 2021 16:57:13
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:11

FDA-CBER-2022-1614-0870594

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:17:47
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:17:35
User entered 'Day 16 (Day 16)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '18 Dec 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:39:23
User entered '15 Dec 2020'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '0'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '99' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:39:23
User entered '97'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User entered '%'	System	16 Dec 2020 19:08:37

FDA-CBER-2022-1614-0870599

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '98.7' F reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:39:23
User entered '98.5' F	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

FDA-CBER-2022-1614-0870600

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

FDA-CBER-2022-1614-0870602

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

FDA-CBER-2022-1614-0870603

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

FDA-CBER-2022-1614-0870605

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

FDA-CBER-2022-1614-0870606

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

FDA-CBER-2022-1614-0870607

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

FDA-CBER-2022-1614-0870608

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

FDA-CBER-2022-1614-0870609

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

FDA-CBER-2022-1614-0870610

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

FDA-CBER-2022-1614-0870611

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

FDA-CBER-2022-1614-0870612

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

FDA-CBER-2022-1614-0870613

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

FDA-CBER-2022-1614-0870614

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

FDA-CBER-2022-1614-0870615

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (16)
Generated On: 09 Jun 2021 16:57:13
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:08:37

FDA-CBER-2022-1614-0870616

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:40:08
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '19 Dec 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:40:08
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 19:32:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 19:32:36
User entered '15 Dec 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:36
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 19:32:26
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '0'	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

FDA-CBER-2022-1614-0870619

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '98' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:40:08
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
User entered '%'	System	28 Dec 2020 19:40:08
User entered empty.	System	17 Dec 2020 19:32:26

FDA-CBER-2022-1614-0870621

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered '97.8' F reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:40:08
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:40:08
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:40:08
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:40:08
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:40:08
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:40:08
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

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US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:40:08
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:40:08
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

FDA-CBER-2022-1614-0870629

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:40:08
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:40:08
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

FDA-CBER-2022-1614-0870631

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:40:08
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:40:08
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

FDA-CBER-2022-1614-0870633

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:40:08
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:40:08
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

FDA-CBER-2022-1614-0870635

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:40:08
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:40:08
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Symptom Log (17)
Generated On: 09 Jun 2021 16:57:13
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:38:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 18:26:49
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:40:08
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Dec 2020 19:32:26

FDA-CBER-2022-1614-0870638

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 16:57:13
Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:26
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:03:49
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:03:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:39:03
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	22 Apr 2021 20:38:38
DataPoint Un-verified.	Karol Moore (b) (4) (b) (4)	22 Apr 2021 19:23:13
Signature has been broken.	Karol Moore (b) (4) (b) (4)	22 Apr 2021 19:23:13
User entered '10 Dec 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	22 Apr 2021 19:23:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:40:34
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	07 Apr 2021 18:09:08
User entered '04 Dec 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	04 Mar 2021 19:52:04
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 18:40:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 18:40:29
User entered '10 Dec 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:40:29
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 18:40:15
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:40:15

FDA-CBER-2022-1614-0870639

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 16:57:13
Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:26
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:03:49
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:03:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:40:34
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	07 Apr 2021 18:09:08
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:40:15

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 16:57:13
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:26
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:03:49
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:03:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:40:34
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	07 Apr 2021 18:09:08
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	21 Dec 2020 18:44:39
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'CONFIRMED' (Site from System).	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:40:41
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	18 Dec 2020 18:40:15
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:40:15

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 16:57:13
Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:26
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:03:49
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:03:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:39:03
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	22 Apr 2021 20:38:38
DataPoint Un-verified.	Karol Moore (b) (4) (b) (4)	22 Apr 2021 19:23:13
Signature has been broken.	Karol Moore (b) (4) (b) (4)	22 Apr 2021 19:23:13
User entered '10 Dec 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	22 Apr 2021 19:23:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:40:34
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 04-DEC-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample for 04-DEC-2020 is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date, else, please ship the sample and provide the details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 12:22:04
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	07 Apr 2021 18:09:08
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 04-DEC-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample for 04-DEC-2020 is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date, else, please ship the sample and provide the details in the response. Thank you.' answered with 'CORRECT AS ENTERED. SUBJECT WAS OUT OF STATE, DID NOT HAVE SAMPLES SENT TO PPD LAB ON 04DEC2020' (Site from DM).	Karol Moore (b) (4) (b) (4)	07 Apr 2021 15:54:40

US3312095

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:57:13

Date of Test

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 04-DEC-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample for 04-DEC-2020 is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date, else, please ship the sample and provide the details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 07:56:58
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Swab sample dated 10DEC2020 is reported under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:26:56
User closed query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 08:56:38
Query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' answered with 'updated per source' (Site from DM).	Karol Moore (b) (4) (b) (4)	04 Mar 2021 19:52:30
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Swab sample dated 10DEC2020 is reported under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please amend GCL or Preclarus as appropriate. Thank you.' answered with 'updated per source' (Site from DM).	Karol Moore (b) (4) (b) (4)	04 Mar 2021 19:52:24
User entered '04 Dec 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	04 Mar 2021 19:52:04
User opened query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 17:21:07

US3312095

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:57:13

Date of Test

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Swab sample dated 10DEC2020 is reported under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 11:03:45
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per site response, “subject did not perform test at our clinic”; however, corresponding swab sample is entered in EDC for subject #US3312095. Kindly review & confirm if the swab sample collected on 10-DEC-2020 was for this subject, if yes kindly confirm if the sample has been shipped then provide Accession number for tracking else, please ship the sample and provide the tracking details in the response, if not kindly confirm the subject ID for which this swab sample was collected.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 09:57:14
Query 'Per GCL Lab Reconciliation requery: Swab: Per site response, “subject did not perform test at our clinic”; however, corresponding swab sample is entered in EDC for subject #US3312095. Kindly review & confirm if the swab sample collected on 10-DEC-2020 was for this subject, if yes kindly confirm if the sample has been shipped then provide Accession number for tracking else, please ship the sample and provide the tracking details in the response, if not kindly confirm the subject ID for which this swab sample was collected.' answered with 'SAMPLE WAS NOT SHIPPED. SUBJECT WAS OUT OF STATE AND REPORTED TAKING A RT-PCR TEST ON 10-DEC-2020. ' (Site from DM).	Karol Moore (b) (4) (b) (4)	28 Dec 2020 17:30:36

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 16:57:13
Date of Test

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per site response, “subject did not perform test at our clinic”; however, corresponding swab sample is entered in EDC for subject #US3312095. Kindly review & confirm if the swab sample collected on 10-DEC-2020 was for this subject, if yes kindly confirm if the sample has been shipped then provide Accession number for tracking else, please ship the sample and provide the tracking details in the response, if not kindly confirm the subject ID for which this swab sample was collected.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 06:04:40
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 10-DEC-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab 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)	28 Dec 2020 06:04:40
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 10-DEC-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab 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 'SUBJECT DID NOT PERFORM TEST AT OUR CLINIC' (Site from DM).	Karol Moore (b) (4) (b) (4)	22 Dec 2020 19:59:09
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 10-DEC-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab 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)	22 Dec 2020 06:18:28
User entered '10 Dec 2020'	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:40:15

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 16:57:13
Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:26
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	28 Apr 2021 21:58:41
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:03:17
DataPoint Un-verified.	Karol Moore (b) (4) (b) (4)	26 Apr 2021 19:13:18
Signature has been broken.	Karol Moore (b) (4) (b) (4)	26 Apr 2021 19:13:18
User entered 'Saliva Test (Saliva Test)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	26 Apr 2021 19:13:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:03:49
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:03:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:40:34
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	07 Apr 2021 18:09:08
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:40:15

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US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 16:57:13
Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:26
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:03:49
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:03:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:40:34
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	07 Apr 2021 18:09:08
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:40:15

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US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 16:57:13
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)	02 May 2021 02:17:26
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	28 Apr 2021 21:58:41
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:03:17
DataPoint Un-verified.	Karol Moore (b) (4) (b) (4)	26 Apr 2021 17:47:36
Signature has been broken.	Karol Moore (b) (4) (b) (4)	26 Apr 2021 17:47:36
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	26 Apr 2021 17:47:36
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:03:49
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:03:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:40:34
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	07 Apr 2021 18:09:08
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:40:15

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 16:57:13
Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:26
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	28 Apr 2021 21:58:41
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:03:17
DataPoint Un-verified.	Karol Moore (b) (4) (b) (4)	26 Apr 2021 17:47:36
Signature has been broken.	Karol Moore (b) (4) (b) (4)	26 Apr 2021 17:47:36
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	26 Apr 2021 17:47:36
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:03:49
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:03:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:40:34
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	07 Apr 2021 18:09:08
User entered 'UNKNOWN'	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:40:15

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 16:57:13
CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:26
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	28 Apr 2021 21:58:41
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:03:17
DataPoint Un-verified.	Karol Moore (b) (4) (b) (4)	26 Apr 2021 17:47:36
Signature has been broken.	Karol Moore (b) (4) (b) (4)	26 Apr 2021 17:47:36
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	26 Apr 2021 17:47:36
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:03:49
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:03:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:40:34
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	07 Apr 2021 18:09:08
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Jan 2021 18:31:37
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	08 Jan 2021 18:31:37
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Dec 2020 18:40:15
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:40:15

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US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 16:57:13
COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:26
User entered '1'	System	18 Dec 2020 18:40:15

FDA-CBER-2022-1614-0870651

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Respiratory Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Did the subject have Heart Rate ≥ 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

FDA-CBER-2022-1614-0870656

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Heart Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

FDA-CBER-2022-1614-0870664

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
PaO2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

FDA-CBER-2022-1614-0870668

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
High-Flow Oxygen?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Non-Invasive Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Mechanical Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
ECMO?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Evidence of Shock Requires Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Acute Renal Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

FDA-CBER-2022-1614-0870690

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Hepatic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

FDA-CBER-2022-1614-0870692

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Neurologic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

FDA-CBER-2022-1614-0870694

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Clinical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

FDA-CBER-2022-1614-0870696

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Radiographical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

FDA-CBER-2022-1614-0870698

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Admission to an intensive care unit due to SARS-CoV-2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 16:57:13
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Dec 2020 18:41:10

US3312095
Folder: Covid-19 Assessment 04 Dec 2020
Form: Generate Next COVID-19 Assessment
Generated On: 09 Jun 2021 16:57:13
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:41:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	26 Feb 2021 18:17:19

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 09 Jun 2021 16:57:13
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User accepted default value 'Day 3 (Day 3)'	Karol Moore (b) (4) (b) (4)	29 Dec 2020 17:04:23

FDA-CBER-2022-1614-0870704

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 09 Jun 2021 16:57:13
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:41
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	29 Dec 2020 17:04:23

FDA-CBER-2022-1614-0870705

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 09 Jun 2021 16:57:13
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:41
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	29 Dec 2020 17:04:23

FDA-CBER-2022-1614-0870706

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 09 Jun 2021 16:57:13
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User accepted default value 'Day 5 (Day 5)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:12:51

FDA-CBER-2022-1614-0870707

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 09 Jun 2021 16:57:13
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:41
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:12:51

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 09 Jun 2021 16:57:13
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:41
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '10 Dec 2020'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:12:51

FDA-CBER-2022-1614-0870709

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 09 Jun 2021 16:57:13
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User accepted default value 'Day 7 (Day 7)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:13:01

FDA-CBER-2022-1614-0870710

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 09 Jun 2021 16:57:13
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:41
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:13:01

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 09 Jun 2021 16:57:13
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:41
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '12 Dec 2020'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:13:01

FDA-CBER-2022-1614-0870712

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 09 Jun 2021 16:57:13
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User accepted default value 'Day 9 (Day 9)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:13:12

FDA-CBER-2022-1614-0870713

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 09 Jun 2021 16:57:13
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:41
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:13:12

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 09 Jun 2021 16:57:13
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:41
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '14 Dec 2020'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:13:12

FDA-CBER-2022-1614-0870715

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 09 Jun 2021 16:57:13
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User accepted default value 'Day 14 (Day 14)'	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:41:44

FDA-CBER-2022-1614-0870716

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 09 Jun 2021 16:57:13
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:41
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:41:44

FDA-CBER-2022-1614-0870717

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 09 Jun 2021 16:57:13
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:41
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '19 Dec 2020'	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:41:44

FDA-CBER-2022-1614-0870718

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 09 Jun 2021 16:57:13
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User accepted default value 'Day 21 (Day 21)'	Karol Moore (b) (4) (b) (4)	29 Dec 2020 17:04:14

FDA-CBER-2022-1614-0870719

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 09 Jun 2021 16:57:13
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:41
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	29 Dec 2020 17:04:14

FDA-CBER-2022-1614-0870720

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 09 Jun 2021 16:57:13
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:41
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '26 Dec 2020'	Karol Moore (b) (4) (b) (4)	29 Dec 2020 17:04:14

FDA-CBER-2022-1614-0870721

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 09 Jun 2021 16:57:13
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User accepted default value 'Day 28 (Day 28)'	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:35:51

FDA-CBER-2022-1614-0870722

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 09 Jun 2021 16:57:13
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:41
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:35:51

FDA-CBER-2022-1614-0870723

US3312095
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 09 Jun 2021 16:57:13
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:41
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '04 Jan 2021'	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:35:51

US3312095
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:13:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:11:54

FDA-CBER-2022-1614-0870725

US3312095
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:13:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:11:54

FDA-CBER-2022-1614-0870726

US3312095
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
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 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:13:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:11:54

US3312095
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered 'SICKD1'	System	16 Dec 2020 19:11:54

FDA-CBER-2022-1614-0870728

US3312095
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:13:36
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:12:12

FDA-CBER-2022-1614-0870729

US3312095
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:13:36
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:12:12

FDA-CBER-2022-1614-0870730

US3312095
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:13:36
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:12:12

FDA-CBER-2022-1614-0870731

US3312095
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered empty.	System	16 Dec 2020 19:12:12

FDA-CBER-2022-1614-0870732

US3312095
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:13:36
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:12:12

FDA-CBER-2022-1614-0870733

US3312095
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:13:36
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:12:12

FDA-CBER-2022-1614-0870734

US3312095
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:13:36
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:12:12

FDA-CBER-2022-1614-0870735

US3312095
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:13:36
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:12:12

FDA-CBER-2022-1614-0870736

US3312095
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered empty.	System	16 Dec 2020 19:12:12

FDA-CBER-2022-1614-0870737

US3312095
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:13:36
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:12:12

FDA-CBER-2022-1614-0870738

US3312095
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered empty.	System	16 Dec 2020 19:12:12

FDA-CBER-2022-1614-0870739

US3312095
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:13:36
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:12:12

FDA-CBER-2022-1614-0870740

US3312095
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered empty.	System	16 Dec 2020 19:12:12

FDA-CBER-2022-1614-0870741

US3312095
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:13:36
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:12:12

FDA-CBER-2022-1614-0870742

US3312095
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered empty.	System	16 Dec 2020 19:12:12

FDA-CBER-2022-1614-0870743

US3312095
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57

FDA-CBER-2022-1614-0870744

US3312095
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57

FDA-CBER-2022-1614-0870745

US3312095
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:57:13
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:13:39
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:12:16

FDA-CBER-2022-1614-0870746

US3312095
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:57:13
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:13:39
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:12:16

FDA-CBER-2022-1614-0870747

US3312095

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:57:13

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 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:13:44
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User closed query 'Per GCL Lab Reconciliation: As it appears illnes Visit was not done, Please update.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 07:38:07
Query 'Per GCL Lab Reconciliation: As it appears illnes Visit was not done, Please update.' answered with 'CORRECT AS ENTERED. SUBJECT WAS OUT OF TOWN AND COULD NOT COME IN FOR REGULAR ILLNESS VISIT. SUBJECT PROVIDED PROOF OF POSITIVE COVID-19 RESULT, RESULTING IN CONVALESCENT PERIOD' (Site from DM).	Karol Moore (b) (4) (b) (4)	18 Mar 2021 15:24:54
User opened query 'Per GCL Lab Reconciliation: As it appears illnes Visit was not done, Please update.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 13:36:56
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:12:21

US3312095
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 09 Jun 2021 16:57:13
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:13:44
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	16 Dec 2020 19:12:21

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:13:56
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:34:47

FDA-CBER-2022-1614-0870750

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:13:56
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '04 Jan 2021'	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:34:47

FDA-CBER-2022-1614-0870751

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:13:56
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Clinic (Clinic)'	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:34:47

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
User entered 'SICKD28'	System	04 Jan 2021 20:34:47

FDA-CBER-2022-1614-0870753

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:02
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:35:20

FDA-CBER-2022-1614-0870754

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:02
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '04 Jan 2021'	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:35:20

FDA-CBER-2022-1614-0870755

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:02
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '10:13'	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:35:20

FDA-CBER-2022-1614-0870756

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
User entered '04 Jan 2021 10:13'	System	04 Jan 2021 20:35:20

FDA-CBER-2022-1614-0870757

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:02
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:35:20
DataPoint set to visible.	System	04 Jan 2021 20:34:47

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:02
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:35:20
DataPoint set to visible.	System	04 Jan 2021 20:34:47

FDA-CBER-2022-1614-0870759

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:02
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '97.7' F	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:35:20

FDA-CBER-2022-1614-0870760

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:02
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:35:20

FDA-CBER-2022-1614-0870761

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:02
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:35:20

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:02
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '63'	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:35:20

FDA-CBER-2022-1614-0870763

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
User entered 'bpm'	System	04 Jan 2021 20:35:20

FDA-CBER-2022-1614-0870764

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:02
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '14'	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:35:20

FDA-CBER-2022-1614-0870765

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
User entered 'breaths/min'	System	04 Jan 2021 20:35:20

FDA-CBER-2022-1614-0870766

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:02
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '121'	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:35:20

FDA-CBER-2022-1614-0870767

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
User entered 'mmHg'	System	04 Jan 2021 20:35:20

FDA-CBER-2022-1614-0870768

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:02
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '67'	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:35:20

FDA-CBER-2022-1614-0870769

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
User entered 'mmHg'	System	04 Jan 2021 20:35:20

FDA-CBER-2022-1614-0870770

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59

FDA-CBER-2022-1614-0870771

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:57:13
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59

FDA-CBER-2022-1614-0870772

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:57:13
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:35:30

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:57:13
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '04 Jan 2021'	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:35:30

FDA-CBER-2022-1614-0870774

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 09 Jun 2021 16:57:13
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:12
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:35:40

FDA-CBER-2022-1614-0870775

US3312095
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 09 Jun 2021 16:57:13
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:12
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '04 Jan 2021'	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:35:40

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:49
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Apr 2021 18:04:50

FDA-CBER-2022-1614-0870777

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:49
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Apr 2021 18:04:50

FDA-CBER-2022-1614-0870778

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
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 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:14:49
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Apr 2021 18:04:50

FDA-CBER-2022-1614-0870779

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:57:13
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered 'UNBLND_DECIDE'	System	01 Apr 2021 18:04:50

FDA-CBER-2022-1614-0870780

US3312095

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User closed query 'Per CDM; Per IRT: Informed Consent Date is missing; Kindly update the data, Else clarify. Thank you!' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 04:11:11
Query 'Per CDM; Per IRT: Informed Consent Date is missing; Kindly update the data, Else clarify. Thank you!' answered with 'NA. SUBJECT UNBLINDED UNDER AMENDMENT 6, VIA PHONE, THEN DISCONTINUED FROM STUDY. SUBJECT DID NOT COME IN FOR UNBLINDING VISIT.' (Site from DM).	Karol Moore (b) (4) (b) (4)	22 Apr 2021 14:22:08
User opened query 'Per CDM; Per IRT: Informed Consent Date is missing; Kindly update the data, Else clarify. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 07:49:37
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Apr 2021 18:05:14

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:57:13
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Apr 2021 19:42:41
Signature has been broken.	Karol Moore (b) (4) (b) (4)	13 Apr 2021 14:27:51
User entered '0' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	13 Apr 2021 14:27:51
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '1'	Karol Moore (b) (4) (b) (4)	01 Apr 2021 18:05:14

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:57:13
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	01 Apr 2021 18:05:14

FDA-CBER-2022-1614-0870783

US3312095

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User closed query 'Per CDM:'NA unblinded under A5 and study discontinued' is ticked but subject was unblinded under A6 as per IRT, please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 06:38:13
Query 'Per CDM:'NA unblinded under A5 and study discontinued' is ticked but subject was unblinded under A6 as per IRT, please review and reconcile. ' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	13 Apr 2021 14:28:08
User opened query 'Per CDM:'NA unblinded under A5 and study discontinued' is ticked but subject was unblinded under A6 as per IRT, please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 04:44:07
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	09 Apr 2021 15:57:18
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 field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 10:13:52
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 field.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	08 Apr 2021 18:29:08
Signature has been broken.	Karol Moore (b) (4) (b) (4)	08 Apr 2021 18:29:04
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	08 Apr 2021 18:29:04
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 field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:45:17
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Amendment 5 (Amendment 5)'	Karol Moore (b) (4) (b) (4)	01 Apr 2021 18:05:14

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:57:13
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '10 Mar 2021'	Karol Moore (b) (4) (b) (4)	01 Apr 2021 18:05:14

FDA-CBER-2022-1614-0870785

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:57:13
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Placebo (Placebo)'	Karol Moore (b) (4) (b) (4)	01 Apr 2021 18:05:14

FDA-CBER-2022-1614-0870786

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:57:13
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Placebo (Placebo)'	Karol Moore (b) (4) (b) (4)	01 Apr 2021 18:05:14

FDA-CBER-2022-1614-0870787

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:57:13
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Placebo (Placebo)'	Karol Moore (b) (4) (b) (4)	01 Apr 2021 18:05:14

FDA-CBER-2022-1614-0870788

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:57:13
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Apr 2021 18:05:14

FDA-CBER-2022-1614-0870789

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:57:13
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '1'	System	01 Apr 2021 18:05:14

FDA-CBER-2022-1614-0870790

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:57:13
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered empty.	System	01 Apr 2021 18:05:14

FDA-CBER-2022-1614-0870791

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:57:13
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Apr 2021 18:05:18

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:57:13
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Apr 2021 18:05:18

FDA-CBER-2022-1614-0870793

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:57:13
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Apr 2021 18:05:18

FDA-CBER-2022-1614-0870794

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:57:13
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered empty.	System	01 Apr 2021 18:05:18

FDA-CBER-2022-1614-0870795

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 16:57:13
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Apr 2021 18:04:27

FDA-CBER-2022-1614-0870796

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 16:57:13
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Apr 2021 18:04:27

FDA-CBER-2022-1614-0870797

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 16:57:13
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Apr 2021 18:04:27

FDA-CBER-2022-1614-0870798

US3312095
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 16:57:13
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered empty.	System	01 Apr 2021 18:04:27

FDA-CBER-2022-1614-0870799

US3312095
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 16:57:13
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:56
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered 'Yes (Y)'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:13:58

FDA-CBER-2022-1614-0870800

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:13
User entered 'USA-US300-2020-mRNA-1273-P301000017'	System	08 Dec 2020 13:53:39
User entered 'New'	(b) (4), (b) (6)	08 Dec 2020 13:53:39

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User closed query 'Per CDM: Adverse event term reported as 'Symptomatic Covid-19', However please confirm if this condition is COVID-19 infection and update accordingly to capture the condition.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 15:59:39
Query 'Per CDM: Adverse event term reported as 'Symptomatic Covid-19', However please confirm if this condition is COVID-19 infection and update accordingly to capture the condition.' answered with 'correctly reported per CRF Guidelines' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 21:16:24
User opened query 'Per CDM: Adverse event term reported as 'Symptomatic Covid-19', However please confirm if this condition is COVID-19 infection and update accordingly to capture the condition.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 16:19:29
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 20:30:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 20:30:52
Data point term sent to Coder	System	07 Dec 2020 20:30:11
User entered 'Symptomatic Covid-19'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870802

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered 'Yes (Y)'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered 'No (N)'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870804

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered 'Yes (Y)'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User closed query 'PV Query: Please confirm the event start date for when the subject began to experience symptoms. It was reported symptoms started on 03 Dec 2020 with positive AG test. Currently event start date was on 01 Dec 2020. If event start date is to remain as 01 Dec 2020, please clarify when symptoms started and or when subject had positive AG test.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 19:07:01
User entered '03 Dec 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	29 Dec 2020 16:35:57
Query 'PV Query: Please confirm the event start date for when the subject began to experience symptoms. It was reported symptoms started on 03 Dec 2020 with positive AG test. Currently event start date was on 01 Dec 2020. If event start date is to remain as 01 Dec 2020, please clarify when symptoms started and or when subject had positive AG test.' answered with 'CORRECT AS ENTERED. SYMPTOMS STARTED ON 01DEC2020, WHICH PROMPTED A TEST TO BE TAKEN ON 03DEC2020' (Site from Safety).	Karol Moore (b) (4) (b) (4)	28 Dec 2020 19:44:30
User opened query 'PV Query: Please confirm the event start date for when the subject began to experience symptoms. It was reported symptoms started on 03 Dec 2020 with positive AG test. Currently event start date was on 01 Dec 2020. If event start date is to remain as 01 Dec 2020, please clarify when symptoms started and or when subject had positive AG test.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 15:42:02
User entered '01 Dec 2020'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870806

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered empty.	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870807

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered empty.	System	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870808

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	29 Dec 2020 16:36:08
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	29 Dec 2020 16:36:08
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	29 Dec 2020 16:35:57
User entered 'Yes (Y)'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870809

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User closed query 'PV Query: Please consider updating event stop date; stop date should be when all symptoms have resolved (13 Dec 2020). The event end date is reported as 12 Dec 2020; however, runny nose was still reported on 12 Jan 2021. If not updated, please clarify. ' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 19:01:21
Query 'PV Query: Please consider updating event stop date; stop date should be when all symptoms have resolved (13 Dec 2020). The event end date is reported as 12 Dec 2020; however, runny nose was still reported on 12 Jan 2021. If not updated, please clarify. ' answered with 'CORRECT AS ENTERED. SUBJECT DID NOT HAVE SYMPTOMS OF RUNNY NOSE ON 12JAN2021' (Site from Safety).	Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:00:02
User opened query 'PV Query: Please consider updating event stop date; stop date should be when all symptoms have resolved (13 Dec 2020). The event end date is reported as 12 Dec 2020; however, runny nose was still reported on 12 Jan 2021. If not updated, please clarify. ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 19:41:37
User closed query 'PV Query: The event end date is reported as 12 Dec 2020; however, symptoms were still reported on that day. Please clarify event stop date; stop date should be when all symptoms have resolved (no symptoms reported on 13 Dec 2020).' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:13:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'PV Query: The event end date is reported as 12 Dec 2020; however, symptoms were still reported on that day. Please clarify event stop date; stop date should be when all symptoms have resolved (no symptoms reported on 13 Dec 2020).' answered with 'confirmed symptoms ended that day' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 23:53:08
User opened query 'PV Query: The event end date is reported as 12 Dec 2020; however, symptoms were still reported on that day. Please clarify event stop date; stop date should be when all symptoms have resolved (no symptoms reported on 13 Dec 2020).' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 18:30:59
User closed query 'PV Query: Please provide the event end date, when available (when symptoms resolved).' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 19:07:03
Query 'PV Query: Please provide the event end date, when available (when symptoms resolved).' answered with 'UPDATED' (Site from Safety).	Karol Moore (b) (4) (b) (4)	29 Dec 2020 16:36:14
User entered '12 Dec 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	29 Dec 2020 16:35:57
User opened query 'PV Query: Please provide the event end date, when available (when symptoms resolved).' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 15:41:36
User entered empty.	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered empty.	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered empty.	System	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870813

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870814

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered 'No (N)'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870815

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered '0'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870816

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered '0'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870817

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered '0'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870818

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered empty.	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870819

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered empty.	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870820

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered empty.	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870821

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered empty.	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870822

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered '0'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870823

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered '0'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870824

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered '0'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870825

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered 'Not Related (NOT RELATED)'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870826

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered 'Not Related (NOT RELATED)'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870827

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered 'Not Applicable (NOT APPLICABLE)'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870828

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered '1'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870829

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered '0'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870830

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered '0'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870831

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 19:07:06
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'UPDATED' (Site from Safety).	Karol Moore (b) (4) (b) (4)	29 Dec 2020 16:36:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	29 Dec 2020 16:35:57
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 15:41:01
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 21:16:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 21:16:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 21:16:32
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 20:30:07
User entered empty.	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
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 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered empty.	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870833

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User closed query 'PV Query: Please clarify symptom log as Day 13 and Day 16 of symptom log are both marked as 15 Dec 2020.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 14:32:44
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 14:32:41
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'CORRECT AS ENTERED. STATED IN NARRATIVE "NO ASSOCIATED CON MEDS."' (Site from Safety).	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:37:47
Query 'PV Query: Please clarify symptom log as Day 13 and Day 16 of symptom log are both marked as 15 Dec 2020.' answered with 'updated' (Site from Safety).	Karol Moore (b) (4) (b) (4)	04 Jan 2021 20:36:41
User opened query 'PV Query: Please clarify symptom log as Day 13 and Day 16 of symptom log are both marked as 15 Dec 2020.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 14:21:12
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 15:41:16

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Narrative

Audit	User	Time (GMT)
User entered '01Dec subj noted temp 99.8. Ag test neg. 03Dec mildly short of breath, myalgia, blunted taste/smell, no other symptoms. Ag test pos. No associated con meds. Subj (b) (6) now due to new traveling nurse assignment, with unknown return date. Can't do illness visit. Will coordinate convalescent phone visits and testing.'	Carlos Fierro (b) (4) (b) (4)	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870835

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '0'	System	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870836

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '1'	System	07 Dec 2020 20:30:07

FDA-CBER-2022-1614-0870837

US3312095
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:57:13
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57

FDA-CBER-2022-1614-0870838

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 17:32:31
User entered 'USA-US300-2021-mRNA-1273-P301000019'	System	24 Feb 2021 17:31:48
User entered 'New'	(b) (4), (b) (6)	24 Feb 2021 17:31:48

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 23:58:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 23:58:10
Data point term sent to Coder	System	23 Feb 2021 23:57:51
User entered 'pneumonia'	(b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870840

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870841

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 23:57:50

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 23:57:50

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:49:34
User entered '15 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870844

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870845

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered empty.	System	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870846

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:48:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870847

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	10 Mar 2021 23:49:34
User entered '24 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 23:49:34
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Mar 2021 23:49:00
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	10 Mar 2021 23:49:00
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	10 Mar 2021 23:48:39
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Mar 2021 23:48:39
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 23:48:39
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870848

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:36:32
User closed query 'Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:34:52
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 23:50:06
Query 'Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 23:49:43
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 19:16:58
User opened query 'Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 19:16:37
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870849

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered empty.	System	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870850

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870851

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870852

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870853

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870854

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered '1'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870855

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870856

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:35:37
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'sent along with updated SAE narrative ' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 23:52:54
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 19:16:49
User entered '22 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 23:57:50

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870858

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870859

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 23:57:50

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US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 23:57:50

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US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870862

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870863

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870864

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 00:00:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 00:00:28
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 00:00:28
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 23:57:50
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870865

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870866

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 15:58:28
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Con med entered. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 16:26:28
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 05:48:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered '1'	(b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870867

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870868

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:49:00
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870869

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
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 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	10 Mar 2021 23:52:25
User entered 'residual exercise intolerance and neck stiffness' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 23:52:25
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	10 Mar 2021 23:49:00
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 23:57:50

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User closed query 'Per CDM CLR re-query: Thank you for your answer. Please consider adding these which are applicable for Concomitant Procedure form. Thank you!' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:27:36
Query 'Per CDM CLR re-query: Thank you for your answer. Please consider adding these which are applicable for Concomitant Procedure form. Thank you!' answered with 'NOT APPLICABLE. PER CRA GUIDANCE, DIAGNOSTIC PRODECURES ARE NOT REPORTABLE. NO APPLICABLE PROCEDURES TO BE ADDED.' (Site from DM).	Karol Moore (b) (4) (b) (4)	09 Apr 2021 16:53:40
User opened query 'Per CDM CLR re-query: Thank you for your answer. Please consider adding these which are applicable for Concomitant Procedure form. Thank you!' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:43:42
User closed query 'Per DM CLR: SAE Narrative Subject undergone several diagnostic procedures. Please review if all procedures should be added to ConProc page. Please update eCRF as appropriate or provide comment. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:43:03
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	08 Apr 2021 15:44:13
Query 'Per DM CLR: SAE Narrative Subject undergone several diagnostic procedures. Please review if all procedures should be added to ConProc page. Please update eCRF as appropriate or provide comment. ' answered with 'Not applicable to enter all diagnostic tests on CM log per CRA-only procedures done. See medical records sent to PVG also. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 15:25:34
User opened query 'Per DM CLR: SAE Narrative Subject undergone several diagnostic procedures. Please review if all procedures should be added to ConProc page. Please update eCRF as appropriate or provide comment. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 14:05:21

FDA-CBER-2022-1614-0870871

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Narrative

Audit	User	Time (GMT)
User closed query 'Per CDM CLR re-query: Thank you for your answer. However, please consider adding also procedures under Concomitant Procedure form. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 09:33:11
Query 'Per CDM CLR re-query: Thank you for your answer. However, please consider adding also procedures under Concomitant Procedure form. Thank you!' answered with 'See medical records discharge summary along with updated SAE narrative sent to Safety team 10Mar2021' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 17:25:10
Signature has been broken.	(b) (4), (b) (6)	18 Mar 2021 17:23:09

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Narrative

Audit	User	Time (GMT)
User entered '23 Y/O FEMALE TRAVELLING NURSE WITH H/O ASTHMA, SEASONAL ALLERGIES, AND SYMPTOMATIC COVID IN EARLY DEC2020 DEVELOPED SORE THROAT WITH ENLARGED ANTERIOR CERVICAL LYMPH NODE AND HEADACHE ON 15FEB21 THAT INCREASED IN SEVERITY PROMPTING ER VISIT; CT HEAD AND NECK ON SAME DAY WERE NEGATIVE AND SUBJECT WAS D/C'D TO HOME. ON 17FEB20 SUBJECT DEVELOPED FEVER, SHORTNESS OF AIR AND CHEST PAIN FOR WHICH SHE RETURNED TO ER AND RECEIVED IV FLUIDS AND HAD NEGATIVE CXR, REPEAT CT HEAD, AND ECHOCARDIOGRAM AND WAS D/C'D TO HOME ON AUGMENTIN AND ZPAC. ON 19FEB20 SUBJECT CONTINUED TO BE ILL AND HER PCP DIRECTLY ADMITTED HER TO A DIFFERENT HOSPITAL WHERE PULMONARY SCANS RULED OUT PE'S BUT CXR REVEALED BILATERAL PNEUMONIA AND LP WAS CONSISTENT WITH ASEPTIC MENINGITIS. SHE WAS TREATED WITH STEROIDS, OXYGEN, STEROIDS, VANCOMYCIN, ZOSYN, AND LEVAQUIN AND D/C'D TO HOME ON 22FEB20 ON ORAL LEVAQUIN AND DEXAMETHASONE. TODAY SUBJECT HAS MILD HEADACHE, FATIGUE, AND SHORTNESS OF AIR. WILL PROCURE MEDICAL RECORDS. SUBJECT DID NOT REPORT SYMPTOMS IN EDIARY AND ILLNESS VISIT WILL NOT BE DONE DUE TO CURRENTLY BEING A TRAVEL NURSE AND LIVES OUT OF TOWN.3/10/21: Med records DC summary and updated Narrative submitted via email due to character length not sufficient' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 17:23:09
User opened query 'Per CDM CLR re-query: Thank you for your answer. However, please consider adding also procedures under Concomitant Procedure form. Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 08:00:06

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Narrative

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates that subject had "CT HEAD AND NECK, CXR, REPEAT CT, ECG, STEROIDS, OXYGEN, STEROIDS, VANCOMYCIN, ZOSYN, AND LEVAQUIN." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 08:00:06
Query 'Per DM CLR: Narrative indicates that subject had "CT HEAD AND NECK, CXR, REPEAT CT, ECG, STEROIDS, OXYGEN, STEROIDS, VANCOMYCIN, ZOSYN, AND LEVAQUIN." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'medication are on CM page...possibly generic names. Diagnostic tests will not be added to CM page as they are not considered procedures ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 22:08:42
User opened query 'Per DM CLR: Narrative indicates that subject had "CT HEAD AND NECK, CXR, REPEAT CT, ECG, STEROIDS, OXYGEN, STEROIDS, VANCOMYCIN, ZOSYN, AND LEVAQUIN." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 05:48:36
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User closed query 'PV Query: Please confirm that dates of "2020" listed in case narrative actually occurred in 2021. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:50:39
User closed query 'PV Query: Provide results of head CT and echocardiogram on 17 Feb 2021. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:50:34
Query 'PV Query: Please confirm that dates of "2020" listed in case narrative actually occurred in 2021. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 23:52:32
Query 'PV Query: Provide results of head CT and echocardiogram on 17 Feb 2021. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 23:51:39

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Narrative

Audit	User	Time (GMT)
User entered '23 Y/O FEMALE TRAVELLING NURSE WITH H/O ASTHMA, SEASONAL ALLERGIES, AND SYMPTOMATIC COVID IN EARLY DEC2020 DEVELOPED SORE THROAT WITH ENLARGED ANTERIOR CERVICAL LYMPH NODE AND HEADACHE ON 15FEB21 THAT INCREASED IN SEVERITY PROMPTING ER VISIT; CT HEAD AND NECK ON SAME DAY WERE NEGATIVE AND SUBJECT WAS D/C'D TO HOME. ON 17FEB20 SUBJECT DEVELOPED FEVER, SHORTNESS OF AIR AND CHEST PAIN FOR WHICH SHE RETURNED TO ER AND RECEIVED IV FLUIDS AND HAD NEGATIVE CXR, REPEAT CT HEAD, AND ECHOCARDIOGRAM AND WAS D/C'D TO HOME ON AUGMENTIN AND ZPAC. ON 19FEB20 SUBJECT CONTINUED TO BE ILL AND HER PCP DIRECTLY ADMITTED HER TO A DIFFERENT HOSPITAL WHERE PULMONARY SCANS RULED OUT PE'S BUT CXR REVEALED BILATERAL PNEUMONIA AND LP WAS CONSISTENT WITH ASEPTIC MENINGITIS. SHE WAS TREATED WITH STEROIDS, OXYGEN, STEROIDS, VANCOMYCIN, ZOSYN, AND LEVAQUIN AND D/C'D TO HOME ON 22FEB20 ON ORAL LEVAQUIN AND DEXAMETHASONE. TODAY SUBJECT HAS MILD HEADACHE, FATIGUE, AND SHORTNESS OF AIR. WILL PROCURE MEDICAL RECORDS. SUBJECT DID NOT REPORT SYMPTOMS IN EDIARY AND ILLNESS VISIT WILL NOT BE DONE DUE TO CURRENTLY BEING A TRAVEL NURSE AND LIVES OUT OF TOWN.' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 23:51:17
User opened query 'PV Query: Please confirm that dates of "2020" listed in case narrative actually occurred in 2021. ' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 19:17:09
User opened query 'PV Query: Provide results of head CT and echocardiogram on 17 Feb 2021. ' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 19:16:18

FDA-CBER-2022-1614-0870875

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Narrative

Audit	User	Time (GMT)
User entered '23 y/o female travelling nurse with h/o asthma, seasonal allergies, and symptomatic Covid in early Dec2020 developed sore throat with enlarged anterior cervical lymph node and headache on 15Feb20 that increased in severity prompting ER visit; CT head and neck on same day were negative and subject was d/c'd to home. On 17Feb20 subject developed fever, shortness of air and chest pain for which she returned to ER and received iv fluids and had negative CXR, repeat CT head, and echocardiogram and was d/c'd to home on augmentin and zpac. On 19Feb20 subject continued to be ill and her PCP directly admitted her to a different hospital where pulmonary scans ruled out PE's but CXR revealed bilateral pneumonia and LP was consistent with aseptic meningitis. She was treated with steroids, oxygen, steroids, vancomycin, zosyn, and levaquin and d/c'd to home on 22Feb20 on oral levaquin and dexamethasone. Today subject has mild headache, fatigue, and shortness of air. Will procure medical records. Subject did not report symptoms in ediary and illness visit will not be done due to currently being a travel nurse and lives out of town.'	(b) (4), (b) (6)	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870876

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '1'	System	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870877

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '1'	System	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870878

US3312095
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:57:13
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '0'	System	23 Feb 2021 23:57:50

FDA-CBER-2022-1614-0870879

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:34:00
User entered 'USA-US300-2021-mRNA-1273-P301000019'	(b) (4), (b) (6)	24 Feb 2021 17:33:54

FDA-CBER-2022-1614-0870880

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Central nervous system and spinal infections, PT: Meningitis aseptic, LLT: Aseptic meningitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 00:06:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 00:06:13
Data point term sent to Coder	System	24 Feb 2021 00:04:58
User entered 'aseptic meningitis'	(b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870881

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870882

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870883

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870884

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:53:55
User entered '15 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870885

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870886

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered empty.	System	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870887

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:37:01
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:36:55
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 23:54:07
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 23:54:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 23:53:55
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 19:18:03
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 19:17:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870888

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered '06 Mar 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:53:55
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 00:04:45

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870890

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered empty.	System	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870891

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870892

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870893

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870894

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870895

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered '1'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870896

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870897

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:37:05
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'sent per query, with updated SAE narrative' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 23:54:28
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 19:18:13
User entered '22 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 00:04:45

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870899

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870900

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870901

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870902

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870903

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870904

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870905

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870906

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870907

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 07:57:25
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'CM present' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 22:10:04
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 05:53:06
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered '1'	(b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870908

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870909

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:53:55
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870910

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
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 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:45:47
User entered 'ongoing exercise intolerance and neck stiffness' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:53:55
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870911

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	08 Apr 2021 15:44:13
User closed query 'Per DM CLR: Narrative = PULMONARY SCANS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:07:56
User closed query 'Per DM CLR: Narrative = CXR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:07:54
User closed query 'Per DM CLR: Narrative = LP. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:07:52
User closed query 'Per DM CLR: Narrative = CT HEAD AND NECK ON SAME DAY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:07:50
User closed query 'Per DM CLR: Narrative = NEGATIVE CXR, REPEAT CT HEAD, AND ECHOCARDIOGRAM. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:07:48
Query 'Per DM CLR: Narrative = PULMONARY SCANS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Not a procedure, diagnostic only-also sent in email to safety team' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 23:21:50

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Narrative

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = CT HEAD AND NECK ON SAME DAY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Not a procedure, diagnostic only-also sent in email to safety team' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 23:21:47
Query 'Per DM CLR: Narrative = NEGATIVE CXR, REPEAT CT HEAD, AND ECHOCARDIOGRAM. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Not a procedure, diagnostic only-also sent in email to safety team' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 23:21:43
Query 'Per DM CLR: Narrative = LP. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Not a procedure, diagnostic only-also sent in email to safety team' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 23:21:39
Query 'Per DM CLR: Narrative = CXR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Not a procedure, diagnostic only-also sent in email to safety team' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 23:21:36
User opened query 'Per DM CLR: Narrative = LP. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 02:50:29
User opened query 'Per DM CLR: Narrative = CXR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 02:50:22
User opened query 'Per DM CLR: Narrative = PULMONARY SCANS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 02:50:16

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Narrative

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = NEGATIVE CXR, REPEAT CT HEAD, AND ECHOCARDIOGRAM. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 02:50:10
User opened query 'Per DM CLR: Narrative = CT HEAD AND NECK ON SAME DAY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 02:50:03
User closed query 'PV Query: Please confirm if echocardiogram was done on 17 Feb 2021 or 18 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 12:50:22
Query 'PV Query: Please confirm if echocardiogram was done on 17 Feb 2021 or 18 Feb 2021.' answered with 'Confirmed 18Feb2021' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 15:11:11
User opened query 'PV Query: Please confirm if echocardiogram was done on 17 Feb 2021 or 18 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 15:02:08

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Narrative

Audit	User	Time (GMT)
User entered '23 Y/O FEMALE TRAVELLING NURSE WITH H/O ASTHMA, SEASONAL ALLERGIES, AND SYMPTOMATIC COVID IN EARLY DEC2020 DEVELOPED SORE THROAT WITH ENLARGED ANTERIOR CERVICAL LYMPH NODE AND HEADACHE ON 15FEB21 THAT INCREASED IN SEVERITY PROMPTING ER VISIT; CT HEAD AND NECK ON SAME DAY WERE NEGATIVE AND SUBJECT WAS D/C'D TO HOME. ON 17FEB20 SUBJECT DEVELOPED FEVER, SHORTNESS OF AIR AND CHEST PAIN FOR WHICH SHE RETURNED TO ER AND RECEIVED IV FLUIDS AND HAD NEGATIVE CXR, REPEAT CT HEAD, AND ECHOCARDIOGRAM AND WAS D/C'D TO HOME ON AUGMENTIN AND ZPAC. ON 19FEB20 SUBJECT CONTINUED TO BE ILL AND HER PCP DIRECTLY ADMITTED HER TO A DIFFERENT HOSPITAL WHERE PULMONARY SCANS RULED OUT PE'S BUT CXR REVEALED BILATERAL PNEUMONIA AND LP WAS CONSISTENT WITH ASEPTIC MENINGITIS. SHE WAS TREATED WITH STEROIDS, OXYGEN, STEROIDS, VANCOMYCIN, ZOSYN, AND LEVAQUIN AND D/C'D TO HOME ON 22FEB20 ON ORAL LEVAQUIN AND DEXAMETHASONE. TODAY SUBJECT HAS MILD HEADACHE, FATIGUE, AND SHORTNESS OF AIR. WILL PROCURE MEDICAL RECORDS. COVID TEST NEGATIVE IN HOSPITAL 19FEB2021. 10Mar2021 MEDRECORDS DC SUMMARY AND UPDATED NARRATIVE SUBMITTED VIA EMAIL DUE TO CHARACTER LENGTH NOT SUFFICIENT' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 17:24:08
Signature has been broken.	(b) (4), (b) (6)	18 Mar 2021 17:23:42

FDA-CBER-2022-1614-0870915

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Narrative

Audit	User	Time (GMT)
User entered '23 Y/O FEMALE TRAVELLING NURSE WITH H/O ASTHMA, SEASONAL ALLERGIES, AND SYMPTOMATIC COVID IN EARLY DEC2020 DEVELOPED SORE THROAT WITH ENLARGED ANTERIOR CERVICAL LYMPH NODE AND HEADACHE ON 15FEB21 THAT INCREASED IN SEVERITY PROMPTING ER VISIT; CT HEAD AND NECK ON SAME DAY WERE NEGATIVE AND SUBJECT WAS D/C'D TO HOME. ON 17FEB20 SUBJECT DEVELOPED FEVER, SHORTNESS OF AIR AND CHEST PAIN FOR WHICH SHE RETURNED TO ER AND RECEIVED IV FLUIDS AND HAD NEGATIVE CXR, REPEAT CT HEAD, AND ECHOCARDIOGRAM AND WAS D/C'D TO HOME ON AUGMENTIN AND ZPAC. ON 19FEB20 SUBJECT CONTINUED TO BE ILL AND HER PCP DIRECTLY ADMITTED HER TO A DIFFERENT HOSPITAL WHERE PULMONARY SCANS RULED OUT PE'S BUT CXR REVEALED BILATERAL PNEUMONIA AND LP WAS CONSISTENT WITH ASEPTIC MENINGITIS. SHE WAS TREATED WITH STEROIDS, OXYGEN, STEROIDS, VANCOMYCIN, ZOSYN, AND LEVAQUIN AND D/C'D TO HOME ON 22FEB20 ON ORAL LEVAQUIN AND DEXAMETHASONE. TODAY SUBJECT HAS MILD HEADACHE, FATIGUE, AND SHORTNESS OF AIR. WILL PROCURE MEDICAL RECORDS. COVID TEST NEGATIVE IN HOSPITAL 19FEB2021 Medrecords DC summary and updated Narrative submitted via email due to character length not sufficient' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 17:23:42
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:45:47
User closed query 'PV Query: Please confirm that dates of "2020" listed in case narrative actually occurred in 2021. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:49:16
User closed query 'PV Query: Provide results of head CT and echocardiogram on 17 Feb 2021. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:37:13

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please confirm that dates of "2020" listed in case narrative actually occurred in 2021. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 23:54:55
Query 'PV Query: Provide results of head CT and echocardiogram on 17 Feb 2021. ' answered with 'udpated' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 23:54:51
User entered '23 Y/O FEMALE TRAVELLING NURSE WITH H/O ASTHMA, SEASONAL ALLERGIES, AND SYMPTOMATIC COVID IN EARLY DEC2020 DEVELOPED SORE THROAT WITH ENLARGED ANTERIOR CERVICAL LYMPH NODE AND HEADACHE ON 15FEB21 THAT INCREASED IN SEVERITY PROMPTING ER VISIT; CT HEAD AND NECK ON SAME DAY WERE NEGATIVE AND SUBJECT WAS D/C'D TO HOME. ON 17FEB20 SUBJECT DEVELOPED FEVER, SHORTNESS OF AIR AND CHEST PAIN FOR WHICH SHE RETURNED TO ER AND RECEIVED IV FLUIDS AND HAD NEGATIVE CXR, REPEAT CT HEAD, AND ECHOCARDIOGRAM AND WAS D/C'D TO HOME ON AUGMENTIN AND ZPAC. ON 19FEB20 SUBJECT CONTINUED TO BE ILL AND HER PCP DIRECTLY ADMITTED HER TO A DIFFERENT HOSPITAL WHERE PULMONARY SCANS RULED OUT PE'S BUT CXR REVEALED BILATERAL PNEUMONIA AND LP WAS CONSISTENT WITH ASEPTIC MENINGITIS. SHE WAS TREATED WITH STEROIDS, OXYGEN, STEROIDS, VANCOMYCIN, ZOSYN, AND LEVAQUIN AND D/C'D TO HOME ON 22FEB20 ON ORAL LEVAQUIN AND DEXAMETHASONE. TODAY SUBJECT HAS MILD HEADACHE, FATIGUE, AND SHORTNESS OF AIR. WILL PROCURE MEDICAL RECORDS. COVID TEST NEGATIVE IN HOSPITAL 19FEB2021' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 23:54:46
User opened query 'PV Query: Please confirm that dates of "2020" listed in case narrative actually occurred in 2021. ' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 19:17:45

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Provide results of head CT and echocardiogram on 17 Feb 2021. ' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 19:17:30
User entered '23 y/o female travelling nurse with h/o asthma, seasonal allergies, and symptomatic Covid in early Dec2020 developed sore throat with enlarged anterior cervical lymph node and headache on 15Feb20 that increased in severity prompting ER visit; CT head and neck on same day were negative and subject was d/c'd to home. On 17Feb20 subject developed fever, shortness of air and chest pain for which she returned to ER and received iv fluids and had negative CXR, repeat CT head, and echocardiogram and was d/c'd to home on augmentin and zpac. On 19Feb20 subject continued to be ill and her PCP directly admitted her to a different hospital where pulmonary scans ruled out PE's but CXR revealed bilateral pneumonia and LP was consistent with aseptic meningitis. She was treated with steroids, oxygen, steroids, vancomycin, zosyn, and levaquin and d/c'd to home on 22Feb20 on oral levaquin and dexamethasone. Today subject has mild headache, fatigue, and shortness of air. Will procure medical records. Covid test negative in hospital 19feb2021'	(b) (4), (b) (6)	24 Feb 2021 00:04:45

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '1'	System	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870919

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '1'	System	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870920

US3312095
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:57:13
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '0'	System	24 Feb 2021 00:04:45

FDA-CBER-2022-1614-0870921

US3312095

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:57:13

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:37
User closed query 'Per CDM: per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:16:52
Query 'Per CDM: per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF.' answered with 'SUBJECT RECEIVED EAU VACCINE AFTER DISCONTIUNATION IN STUDY. EAU VACCINE UNKOWN' (Site from DM).	Monica Atwood (b) (4) (b) (4)	07 Apr 2021 17:38:12
User opened query 'Per CDM: per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:32:06
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:56:05

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Sep 2020 17:58:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Sep 2020 17:58:48
Data point term sent to Coder	System	07 Sep 2020 17:57:33
User entered 'multivitamin'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:56:33

FDA-CBER-2022-1614-0870923

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:56:33

FDA-CBER-2022-1614-0870924

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'health maintenance'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:56:33

FDA-CBER-2022-1614-0870925

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered '1'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:56:33

FDA-CBER-2022-1614-0870926

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'tablet (TABLET)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:56:33

FDA-CBER-2022-1614-0870927

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:56:33

FDA-CBER-2022-1614-0870928

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:56:33

FDA-CBER-2022-1614-0870929

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:56:33

FDA-CBER-2022-1614-0870930

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:56:33

FDA-CBER-2022-1614-0870931

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:56:33

FDA-CBER-2022-1614-0870932

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'un UNK 2015'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:56:33

FDA-CBER-2022-1614-0870933

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered '0'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:56:33

FDA-CBER-2022-1614-0870934

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:56:33

FDA-CBER-2022-1614-0870935

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:56:33

FDA-CBER-2022-1614-0870936

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:56:33

FDA-CBER-2022-1614-0870937

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '1'	System	07 Sep 2020 17:56:33

FDA-CBER-2022-1614-0870938

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '1'	System	07 Sep 2020 17:56:33

FDA-CBER-2022-1614-0870939

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '804 (804)'	System	07 Sep 2020 17:56:33

FDA-CBER-2022-1614-0870940

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Sep 2020 17:58:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Sep 2020 17:58:48
Data point term sent to Coder	System	07 Sep 2020 17:57:33
User entered 'vitamin d'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:15

FDA-CBER-2022-1614-0870941

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:15

FDA-CBER-2022-1614-0870942

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'health maintenance'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:15

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User closed query ' Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 15:33:46
Query ' Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	13 Nov 2020 15:13:44
User entered '3000' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	13 Nov 2020 15:13:40
User opened query ' Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 06:10:23
User entered '1'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:15

FDA-CBER-2022-1614-0870944

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'IU (IU)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	13 Nov 2020 15:13:40
User entered 'tablet (TABLET)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:15

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:15

FDA-CBER-2022-1614-0870946

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:15

FDA-CBER-2022-1614-0870947

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:15

FDA-CBER-2022-1614-0870948

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:15

FDA-CBER-2022-1614-0870949

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:15

FDA-CBER-2022-1614-0870950

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'un UNK 2019'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:15

FDA-CBER-2022-1614-0870951

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered '0'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:15

FDA-CBER-2022-1614-0870952

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:15

FDA-CBER-2022-1614-0870953

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:15

FDA-CBER-2022-1614-0870954

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:15

FDA-CBER-2022-1614-0870955

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '1'	System	07 Sep 2020 17:57:15

FDA-CBER-2022-1614-0870956

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '1'	System	07 Sep 2020 17:57:15

FDA-CBER-2022-1614-0870957

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '804 (804)'	System	07 Sep 2020 17:57:15

FDA-CBER-2022-1614-0870958

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Sep 2020 17:59:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Sep 2020 17:59:49
Data point term sent to Coder	System	07 Sep 2020 17:58:34
User entered 'mirena'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:56

FDA-CBER-2022-1614-0870959

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:56

FDA-CBER-2022-1614-0870960

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'birth control'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:56

FDA-CBER-2022-1614-0870961

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered '1'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:56

FDA-CBER-2022-1614-0870962

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'Other (OTHER)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:56

FDA-CBER-2022-1614-0870963

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'intrauterine device'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:56

FDA-CBER-2022-1614-0870964

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'other (OTHER)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:56

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'once every 5 years'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:56

FDA-CBER-2022-1614-0870966

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'Other (OTHER)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:56

FDA-CBER-2022-1614-0870967

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'intrauterine'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:56

FDA-CBER-2022-1614-0870968

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:56

FDA-CBER-2022-1614-0870969

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered '0'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:56

FDA-CBER-2022-1614-0870970

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:56

FDA-CBER-2022-1614-0870971

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:56

FDA-CBER-2022-1614-0870972

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:57:56

FDA-CBER-2022-1614-0870973

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered empty.	System	07 Sep 2020 17:57:56

FDA-CBER-2022-1614-0870974

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered empty.	System	07 Sep 2020 17:57:56

FDA-CBER-2022-1614-0870975

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered empty.	System	07 Sep 2020 17:57:56

FDA-CBER-2022-1614-0870976

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User closed query 'Per ETRTR, Please note that according to AE PNEUMONIA, subject was administered concomitant medication but no conmeds are listed for this condition. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 21:01:24
User closed query 'Per ETRTR, Please note that according to AE ASEPTIC MENINGITIS, subject was administered concomitant medication but no conmeds are listed for this condition. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 21:01:22
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
Query 'Per ETRTR, Please note that according to AE PNEUMONIA, subject was administered concomitant medication but no conmeds are listed for this condition. Please reconcile.' answered with 'con med entered. ' (Site from CRA).	(b) (4), (b) (6)	15 Mar 2021 16:24:05
Query 'Per ETRTR, Please note that according to AE ASEPTIC MENINGITIS, subject was administered concomitant medication but no conmeds are listed for this condition. Please reconcile.' answered with 'Con meds entered. ' (Site from CRA).	(b) (4), (b) (6)	15 Mar 2021 16:23:50
User opened query 'Per ETRTR, Please note that according to AE PNEUMONIA, subject was administered concomitant medication but no conmeds are listed for this condition. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 20:02:34
User opened query 'Per ETRTR, Please note that according to AE ASEPTIC MENINGITIS, subject was administered concomitant medication but no conmeds are listed for this condition. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 20:01:57

FDA-CBER-2022-1614-0870977

US3312095

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 05:45:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 05:45:47
Data point term sent to Coder	System	07 Sep 2020 17:59:34
User entered 'influenza vaccination'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:59:10

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:59:10

FDA-CBER-2022-1614-0870979

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'seasonal influenza prophylaxis'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:59:10

FDA-CBER-2022-1614-0870980

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered '1'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:59:10

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'Other (OTHER)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:59:10

FDA-CBER-2022-1614-0870982

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'injection'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:59:10

FDA-CBER-2022-1614-0870983

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'once (ONCE)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:59:10

FDA-CBER-2022-1614-0870984

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:59:10

FDA-CBER-2022-1614-0870985

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'Intramuscular (INTRAMUSCULAR)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:59:10

FDA-CBER-2022-1614-0870986

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:59:10

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered '05 Sep 2020'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:59:10

FDA-CBER-2022-1614-0870988

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered '0'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:59:10

FDA-CBER-2022-1614-0870989

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:59:10

FDA-CBER-2022-1614-0870990

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered '05 Sep 2020'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:59:10

FDA-CBER-2022-1614-0870991

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	07 Sep 2020 17:59:10

FDA-CBER-2022-1614-0870992

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:45
User entered empty.	System	07 Sep 2020 17:59:10

FDA-CBER-2022-1614-0870993

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:45
User entered empty.	System	07 Sep 2020 17:59:10

FDA-CBER-2022-1614-0870994

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:45
User entered empty.	System	07 Sep 2020 17:59:10

FDA-CBER-2022-1614-0870995

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 09:17:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 09:17:49
Data point term sent to Coder	System	15 Mar 2021 15:07:10
User entered 'Amoxicillin / Clavulanic'	(b) (4), (b) (6)	15 Mar 2021 15:06:12

FDA-CBER-2022-1614-0870996

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:06:12

FDA-CBER-2022-1614-0870997

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'pneumonia'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:06:12

FDA-CBER-2022-1614-0870998

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '875/125'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:06:12

FDA-CBER-2022-1614-0870999

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:06:12

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:06:12

FDA-CBER-2022-1614-0871001

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:06:12

FDA-CBER-2022-1614-0871002

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:06:12

FDA-CBER-2022-1614-0871003

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:06:12

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:06:12

FDA-CBER-2022-1614-0871005

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:06:12

FDA-CBER-2022-1614-0871006

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:06:12

FDA-CBER-2022-1614-0871007

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:06:12

FDA-CBER-2022-1614-0871008

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:06:12

FDA-CBER-2022-1614-0871009

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:06:12

FDA-CBER-2022-1614-0871010

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:48
User entered '3'	System	15 Mar 2021 15:06:12

FDA-CBER-2022-1614-0871011

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:48
User entered '1'	System	15 Mar 2021 15:06:12

FDA-CBER-2022-1614-0871012

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:48
User entered '804 (804)'	System	15 Mar 2021 15:06:12

FDA-CBER-2022-1614-0871013

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:08:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:08:57
Data point term sent to Coder	System	15 Mar 2021 15:08:11
User entered 'Azithromycin'	(b) (4), (b) (6)	15 Mar 2021 15:07:42

FDA-CBER-2022-1614-0871014

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:07:42

FDA-CBER-2022-1614-0871015

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'pneumonia'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:07:42

FDA-CBER-2022-1614-0871016

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '500'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:07:42

FDA-CBER-2022-1614-0871017

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:07:42

FDA-CBER-2022-1614-0871018

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:07:42

FDA-CBER-2022-1614-0871019

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:07:42

FDA-CBER-2022-1614-0871020

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:07:42

FDA-CBER-2022-1614-0871021

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:07:42

FDA-CBER-2022-1614-0871022

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:07:42

FDA-CBER-2022-1614-0871023

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:07:42

FDA-CBER-2022-1614-0871024

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:07:42

FDA-CBER-2022-1614-0871025

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:07:42

FDA-CBER-2022-1614-0871026

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:07:42

FDA-CBER-2022-1614-0871027

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:07:42

FDA-CBER-2022-1614-0871028

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:52
User entered empty.	System	15 Mar 2021 15:07:42

FDA-CBER-2022-1614-0871029

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:52
User entered empty.	System	15 Mar 2021 15:07:42

FDA-CBER-2022-1614-0871030

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:52
User entered empty.	System	15 Mar 2021 15:07:42

FDA-CBER-2022-1614-0871031

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:09:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:09:56
Data point term sent to Coder	System	15 Mar 2021 15:09:11
User entered 'Azithromycin'	(b) (4), (b) (6)	15 Mar 2021 15:09:03

FDA-CBER-2022-1614-0871032

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 15:09:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 15:09:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 15:09:11
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 15:09:03
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 15:09:03

FDA-CBER-2022-1614-0871033

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'pneumonia'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:09:03

FDA-CBER-2022-1614-0871034

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '250'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:09:03

FDA-CBER-2022-1614-0871035

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:09:03

FDA-CBER-2022-1614-0871036

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:09:03

FDA-CBER-2022-1614-0871037

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:09:03

FDA-CBER-2022-1614-0871038

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:09:03

FDA-CBER-2022-1614-0871039

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:09:03

FDA-CBER-2022-1614-0871040

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:09:03

FDA-CBER-2022-1614-0871041

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:09:03

FDA-CBER-2022-1614-0871042

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:09:03

FDA-CBER-2022-1614-0871043

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:09:03

FDA-CBER-2022-1614-0871044

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:09:03

FDA-CBER-2022-1614-0871045

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:09:03

FDA-CBER-2022-1614-0871046

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:55
User entered '1'	System	15 Mar 2021 15:09:03

FDA-CBER-2022-1614-0871047

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:55
User entered '1'	System	15 Mar 2021 15:09:03

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:55
User entered '804 (804)'	System	15 Mar 2021 15:09:03

FDA-CBER-2022-1614-0871049

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:23:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:23:02
Data point term sent to Coder	System	15 Mar 2021 15:22:22
Data point term sent to Coder	System	15 Mar 2021 15:18:16
User entered 'Vancomycin'	(b) (4), (b) (6)	15 Mar 2021 15:17:16

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:17:16

FDA-CBER-2022-1614-0871051

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'pneumonia'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:17:16

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'unk'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:17:16

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:17:16

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:17:16

FDA-CBER-2022-1614-0871055

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:17:16

FDA-CBER-2022-1614-0871056

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:17:16

FDA-CBER-2022-1614-0871057

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:22:22
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4), (b) (6)	15 Mar 2021 15:17:16

FDA-CBER-2022-1614-0871058

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:17:16

FDA-CBER-2022-1614-0871059

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:17:16

FDA-CBER-2022-1614-0871060

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:17:16

FDA-CBER-2022-1614-0871061

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:17:16

FDA-CBER-2022-1614-0871062

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '21 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:17:16

FDA-CBER-2022-1614-0871063

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:17:16

FDA-CBER-2022-1614-0871064

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:59
User entered empty.	System	15 Mar 2021 15:17:16

FDA-CBER-2022-1614-0871065

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:59
User entered empty.	System	15 Mar 2021 15:17:16

FDA-CBER-2022-1614-0871066

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:06:59
User entered empty.	System	15 Mar 2021 15:17:16

FDA-CBER-2022-1614-0871067

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: PIPERACILLIN / TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:22:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:22:58
Data point term sent to Coder	System	15 Mar 2021 15:22:20
User entered 'Piperacillin / Tazobactam'	(b) (4), (b) (6)	15 Mar 2021 15:22:10

FDA-CBER-2022-1614-0871068

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:22:10

FDA-CBER-2022-1614-0871069

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'pneumonia'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:22:10

FDA-CBER-2022-1614-0871070

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '3/0.375'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:22:10

FDA-CBER-2022-1614-0871071

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:22:10

FDA-CBER-2022-1614-0871072

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:22:10

FDA-CBER-2022-1614-0871073

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User entered 'four times daily (QID)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	05 Apr 2021 18:36:02
User entered 'other (OTHER)'	(b) (4), (b) (6)	15 Mar 2021 15:22:10

FDA-CBER-2022-1614-0871074

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User closed query 'Per CDM: Please review the frequency for this medication as "four times daily" is an option provided within the drop-down menu of Frequency. For more information follow the CCGs page 49 and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 06:23:29
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
Query 'Per CDM: Please review the frequency for this medication as "four times daily" is an option provided within the drop-down menu of Frequency. For more information follow the CCGs page 49 and update as needed, else provide clarification. ' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	05 Apr 2021 18:36:16
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	05 Apr 2021 18:36:02
User opened query 'Per CDM: Please review the frequency for this medication as "four times daily" is an option provided within the drop-down menu of Frequency. For more information follow the CCGs page 49 and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 19:29:39
User closed query 'Per CDM: Please clarify if "Q 6 hours" means that subject takes medication every 6 hours. If yes, then please consider selecting from the dropdown "Four times daily". Thank you!' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 19:29:39
Query 'Per CDM: Please clarify if "Q 6 hours" means that subject takes medication every 6 hours. If yes, then please consider selecting from the dropdown "Four times daily". Thank you!' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	18 Mar 2021 15:28:43

US3312095

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
User entered 'EVERY 6 HOURS' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	18 Mar 2021 15:28:38
User opened query 'Per CDM: Please clarify if "Q 6 hours" means that subject takes medication every 6 hours. If yes, then please consider selecting from the dropdown "Four times daily". Thank you!' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:00:19
User entered 'Q 6 hours'	(b) (4), (b) (6)	15 Mar 2021 15:22:10

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:22:10

FDA-CBER-2022-1614-0871077

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:22:10

FDA-CBER-2022-1614-0871078

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:22:10

FDA-CBER-2022-1614-0871079

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:22:10

FDA-CBER-2022-1614-0871080

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:22:10

FDA-CBER-2022-1614-0871081

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '21 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:22:10

FDA-CBER-2022-1614-0871082

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:22:10

FDA-CBER-2022-1614-0871083

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:02
User entered '4'	System	05 Apr 2021 18:36:02
User entered empty.	System	15 Mar 2021 15:22:10

FDA-CBER-2022-1614-0871084

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:02
User entered '1'	System	05 Apr 2021 18:36:02
User entered empty.	System	15 Mar 2021 15:22:10

FDA-CBER-2022-1614-0871085

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:02
User entered '804 (804)'	System	05 Apr 2021 18:36:02
User entered empty.	System	15 Mar 2021 15:22:10

FDA-CBER-2022-1614-0871086

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:53:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:53:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 10:06:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 10:06:49
Data point term sent to Coder	System	15 Mar 2021 15:25:25
User entered 'normal saline'	(b) (4), (b) (6)	15 Mar 2021 15:25:23

FDA-CBER-2022-1614-0871087

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:25:23

FDA-CBER-2022-1614-0871088

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'pneumonia, aseptic meningitis'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:25:23

FDA-CBER-2022-1614-0871089

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '1000'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:25:23

FDA-CBER-2022-1614-0871090

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:25:23

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:25:23

FDA-CBER-2022-1614-0871092

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:25:23

FDA-CBER-2022-1614-0871093

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:25:23

FDA-CBER-2022-1614-0871094

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:25:23

FDA-CBER-2022-1614-0871095

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:25:23

FDA-CBER-2022-1614-0871096

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:25:23

FDA-CBER-2022-1614-0871097

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:25:23

FDA-CBER-2022-1614-0871098

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:25:23

FDA-CBER-2022-1614-0871099

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:25:23

FDA-CBER-2022-1614-0871100

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:25:23

FDA-CBER-2022-1614-0871101

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:07
User entered empty.	System	15 Mar 2021 15:25:23

FDA-CBER-2022-1614-0871102

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:07
User entered empty.	System	15 Mar 2021 15:25:23

FDA-CBER-2022-1614-0871103

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:07
User entered empty.	System	15 Mar 2021 15:25:23

FDA-CBER-2022-1614-0871104

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 09:38:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 09:38:48
Data point term sent to Coder	System	15 Mar 2021 15:29:28
User entered 'Fentanyl'	(b) (4), (b) (6)	15 Mar 2021 15:29:05

FDA-CBER-2022-1614-0871105

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 15:29:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 15:29:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 15:29:18
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 15:29:05
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 15:29:05

FDA-CBER-2022-1614-0871106

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'pneumonia, aseptic meningitis'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:29:05

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '25'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:29:05

FDA-CBER-2022-1614-0871108

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:29:05

FDA-CBER-2022-1614-0871109

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:29:05

FDA-CBER-2022-1614-0871110

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:29:05

FDA-CBER-2022-1614-0871111

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:29:05

FDA-CBER-2022-1614-0871112

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:29:05

FDA-CBER-2022-1614-0871113

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:29:05

FDA-CBER-2022-1614-0871114

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:29:05

FDA-CBER-2022-1614-0871115

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:29:05

FDA-CBER-2022-1614-0871116

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:29:05

FDA-CBER-2022-1614-0871117

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:29:05

FDA-CBER-2022-1614-0871118

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:29:05

FDA-CBER-2022-1614-0871119

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:10
User entered empty.	System	15 Mar 2021 15:29:05

FDA-CBER-2022-1614-0871120

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:10
User entered empty.	System	15 Mar 2021 15:29:05

FDA-CBER-2022-1614-0871121

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:10
User entered empty.	System	15 Mar 2021 15:29:05

FDA-CBER-2022-1614-0871122

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:13
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 16:06:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 16:06:57
Data point term sent to Coder	System	15 Mar 2021 15:31:29
User entered 'Ondansetron'	(b) (4), (b) (6)	15 Mar 2021 15:30:33

FDA-CBER-2022-1614-0871123

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:13
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:30:33

FDA-CBER-2022-1614-0871124

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:13
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'PNEUMONIA, ASEPTIC MENINGITIS'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:30:33

FDA-CBER-2022-1614-0871125

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:13
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '8'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:30:33

FDA-CBER-2022-1614-0871126

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:13
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:30:33

FDA-CBER-2022-1614-0871127

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:13
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:30:33

FDA-CBER-2022-1614-0871128

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:13
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:30:33

FDA-CBER-2022-1614-0871129

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:13
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:30:33

FDA-CBER-2022-1614-0871130

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:13
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:30:33

FDA-CBER-2022-1614-0871131

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:13
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:30:33

FDA-CBER-2022-1614-0871132

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:13
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:30:33

FDA-CBER-2022-1614-0871133

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:13
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:30:33

FDA-CBER-2022-1614-0871134

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:13
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:30:33

FDA-CBER-2022-1614-0871135

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:13
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:30:33

FDA-CBER-2022-1614-0871136

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:13
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:30:33

FDA-CBER-2022-1614-0871137

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:13
User entered empty.	System	15 Mar 2021 15:30:33

FDA-CBER-2022-1614-0871138

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:13
User entered empty.	System	15 Mar 2021 15:30:33

FDA-CBER-2022-1614-0871139

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:13
User entered empty.	System	15 Mar 2021 15:30:33

FDA-CBER-2022-1614-0871140

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:17
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 10:01:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 10:01:49
Data point term sent to Coder	System	15 Mar 2021 15:36:41
User entered 'oxygen'	(b) (4), (b) (6)	15 Mar 2021 15:36:25

FDA-CBER-2022-1614-0871141

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:17
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:36:25

FDA-CBER-2022-1614-0871142

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:17
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'PNEUMONIa'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:36:25

FDA-CBER-2022-1614-0871143

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:17
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0-5'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:36:25

FDA-CBER-2022-1614-0871144

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:17
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:36:25

FDA-CBER-2022-1614-0871145

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:17
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'liter'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:36:25

FDA-CBER-2022-1614-0871146

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:17
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:36:25

FDA-CBER-2022-1614-0871147

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:17
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:36:25

FDA-CBER-2022-1614-0871148

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:17
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Nasal (NASAL)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:36:25

FDA-CBER-2022-1614-0871149

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:17
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:36:25

FDA-CBER-2022-1614-0871150

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:17
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:36:25

FDA-CBER-2022-1614-0871151

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:17
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:36:25

FDA-CBER-2022-1614-0871152

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:17
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:36:25

FDA-CBER-2022-1614-0871153

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:17
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:36:25

FDA-CBER-2022-1614-0871154

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:17
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:36:25

FDA-CBER-2022-1614-0871155

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:17
User entered empty.	System	15 Mar 2021 15:36:25

FDA-CBER-2022-1614-0871156

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:17
User entered empty.	System	15 Mar 2021 15:36:25

FDA-CBER-2022-1614-0871157

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:17
User entered empty.	System	15 Mar 2021 15:36:25

FDA-CBER-2022-1614-0871158

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 10:01:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 10:01:50
Data point term sent to Coder	System	15 Mar 2021 15:37:42
User entered 'oxycodone'	(b) (4), (b) (6)	15 Mar 2021 15:37:31

FDA-CBER-2022-1614-0871159

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:37:31

FDA-CBER-2022-1614-0871160

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'PNEUMONIA, ASEPTIC MENINGITIS'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:37:31

FDA-CBER-2022-1614-0871161

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '5'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:37:31

FDA-CBER-2022-1614-0871162

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:37:31

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:37:31

FDA-CBER-2022-1614-0871164

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:37:31

FDA-CBER-2022-1614-0871165

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:37:31

FDA-CBER-2022-1614-0871166

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:37:31

FDA-CBER-2022-1614-0871167

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:37:31

FDA-CBER-2022-1614-0871168

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:37:31

FDA-CBER-2022-1614-0871169

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:37:31

FDA-CBER-2022-1614-0871170

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:37:31

FDA-CBER-2022-1614-0871171

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:37:31

FDA-CBER-2022-1614-0871172

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:37:31

FDA-CBER-2022-1614-0871173

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:21
User entered empty.	System	15 Mar 2021 15:37:31

FDA-CBER-2022-1614-0871174

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:21
User entered empty.	System	15 Mar 2021 15:37:31

FDA-CBER-2022-1614-0871175

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:21
User entered empty.	System	15 Mar 2021 15:37:31

FDA-CBER-2022-1614-0871176

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LEVAQUIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:48:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:48:57
Data point term sent to Coder	System	15 Mar 2021 15:47:53
User entered 'levaquin'	(b) (4), (b) (6)	15 Mar 2021 15:47:49

FDA-CBER-2022-1614-0871177

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:47:49

FDA-CBER-2022-1614-0871178

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'pneumonia'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:47:49

FDA-CBER-2022-1614-0871179

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '750'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:47:49

FDA-CBER-2022-1614-0871180

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:47:49

FDA-CBER-2022-1614-0871181

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:47:49

FDA-CBER-2022-1614-0871182

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:47:49

FDA-CBER-2022-1614-0871183

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:47:49

FDA-CBER-2022-1614-0871184

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:47:49

FDA-CBER-2022-1614-0871185

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:47:49

FDA-CBER-2022-1614-0871186

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:47:49

FDA-CBER-2022-1614-0871187

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:47:49

FDA-CBER-2022-1614-0871188

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:47:49

FDA-CBER-2022-1614-0871189

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:47:49

FDA-CBER-2022-1614-0871190

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:47:49

FDA-CBER-2022-1614-0871191

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:26
User entered '1'	System	15 Mar 2021 15:47:49

FDA-CBER-2022-1614-0871192

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:26
User entered '1'	System	15 Mar 2021 15:47:49

FDA-CBER-2022-1614-0871193

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:26
User entered '804 (804)'	System	15 Mar 2021 15:47:49

FDA-CBER-2022-1614-0871194

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:53:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:53:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 10:06:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 10:06:49
Data point term sent to Coder	System	15 Mar 2021 15:54:07
User entered 'normal saline'	(b) (4), (b) (6)	15 Mar 2021 15:53:08

FDA-CBER-2022-1614-0871195

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:53:08

FDA-CBER-2022-1614-0871196

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'pneumonia, aseptic meningitis'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:53:08

FDA-CBER-2022-1614-0871197

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '125'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:53:08

FDA-CBER-2022-1614-0871198

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:53:08

FDA-CBER-2022-1614-0871199

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:53:08

FDA-CBER-2022-1614-0871200

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:53:08

FDA-CBER-2022-1614-0871201

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User closed query 'Per CDM: Please clarify the frequency because at the moment is not clear and if possible then please select proper frequency from the droppdown. Thank you!' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 19:31:44
Query 'Per CDM: Please clarify the frequency because at the moment is not clear and if possible then please select proper frequency from the droppdown. Thank you!' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	18 Mar 2021 15:29:38
User entered 'HOURLY' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	18 Mar 2021 15:29:31
User opened query 'Per CDM: Please clarify the frequency because at the moment is not clear and if possible then please select proper frequency from the droppdown. Thank you!' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:01:27
User entered 'q hour'	(b) (4), (b) (6)	15 Mar 2021 15:53:08

FDA-CBER-2022-1614-0871202

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:53:08

FDA-CBER-2022-1614-0871203

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:53:08

FDA-CBER-2022-1614-0871204

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:53:08

FDA-CBER-2022-1614-0871205

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:53:08

FDA-CBER-2022-1614-0871206

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:53:08

FDA-CBER-2022-1614-0871207

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '20 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:53:08

FDA-CBER-2022-1614-0871208

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:53:08

FDA-CBER-2022-1614-0871209

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:29
User entered empty.	System	15 Mar 2021 15:53:08

FDA-CBER-2022-1614-0871210

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:29
User entered empty.	System	15 Mar 2021 15:53:08

FDA-CBER-2022-1614-0871211

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:29
User entered empty.	System	15 Mar 2021 15:53:08

FDA-CBER-2022-1614-0871212

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:58:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:58:57
Data point term sent to Coder	System	15 Mar 2021 15:58:11
User entered 'acetaminophen'	(b) (4), (b) (6)	15 Mar 2021 15:57:50

FDA-CBER-2022-1614-0871213

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 15:58:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 15:58:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 15:58:02
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 15:57:50
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 15:57:50

FDA-CBER-2022-1614-0871214

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'pneumonia aseptic meningitis'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:57:50

FDA-CBER-2022-1614-0871215

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '1000'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:57:50

FDA-CBER-2022-1614-0871216

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:57:50

FDA-CBER-2022-1614-0871217

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:57:50

FDA-CBER-2022-1614-0871218

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:57:50

FDA-CBER-2022-1614-0871219

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:57:50

FDA-CBER-2022-1614-0871220

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:57:50

FDA-CBER-2022-1614-0871221

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:57:50

FDA-CBER-2022-1614-0871222

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:57:50

FDA-CBER-2022-1614-0871223

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:57:50

FDA-CBER-2022-1614-0871224

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:57:50

FDA-CBER-2022-1614-0871225

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '06 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:57:50

FDA-CBER-2022-1614-0871226

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:57:50

FDA-CBER-2022-1614-0871227

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:36
User entered empty.	System	15 Mar 2021 15:57:50

FDA-CBER-2022-1614-0871228

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:36
User entered empty.	System	15 Mar 2021 15:57:50

FDA-CBER-2022-1614-0871229

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:36
User entered empty.	System	15 Mar 2021 15:57:50

FDA-CBER-2022-1614-0871230

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:41
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 10:47:41
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 Mar 2021 10:47:41
Data point term sent to Coder	System	15 Mar 2021 16:01:21
User entered 'ibuprofen'	(b) (4), (b) (6)	15 Mar 2021 16:00:50

FDA-CBER-2022-1614-0871231

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:41
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:00:50

FDA-CBER-2022-1614-0871232

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:41
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'aseptic meningitis'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:00:50

FDA-CBER-2022-1614-0871233

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:41
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '600'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:00:50

FDA-CBER-2022-1614-0871234

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:41
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:00:50

FDA-CBER-2022-1614-0871235

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:41
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:00:50

FDA-CBER-2022-1614-0871236

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:41
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:00:50

FDA-CBER-2022-1614-0871237

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:41
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:00:50

FDA-CBER-2022-1614-0871238

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:41
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:00:50

FDA-CBER-2022-1614-0871239

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:41
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:00:50

FDA-CBER-2022-1614-0871240

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:41
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:00:50

FDA-CBER-2022-1614-0871241

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:41
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:00:50

FDA-CBER-2022-1614-0871242

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:41
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:00:50

FDA-CBER-2022-1614-0871243

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:41
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:00:50

FDA-CBER-2022-1614-0871244

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:41
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:00:50

FDA-CBER-2022-1614-0871245

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:41
User entered empty.	System	15 Mar 2021 16:00:50

FDA-CBER-2022-1614-0871246

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:41
User entered empty.	System	15 Mar 2021 16:00:50

FDA-CBER-2022-1614-0871247

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:41
User entered empty.	System	15 Mar 2021 16:00:50

FDA-CBER-2022-1614-0871248

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:44
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 10:32:44
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 Mar 2021 10:32:44
Data point term sent to Coder	System	15 Mar 2021 16:04:24
Data point term sent to Coder	System	15 Mar 2021 16:03:23
User entered 'ibuprofen'	(b) (4), (b) (6)	15 Mar 2021 16:03:09

FDA-CBER-2022-1614-0871249

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:44
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:03:09

FDA-CBER-2022-1614-0871250

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:44
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'ASEPTIC MENINGITIS' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:03:44
User entered 'pneumonia, aseptic meningitis'	(b) (4), (b) (6)	15 Mar 2021 16:03:09

FDA-CBER-2022-1614-0871251

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:44
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '600'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:03:09

FDA-CBER-2022-1614-0871252

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:44
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:03:09

FDA-CBER-2022-1614-0871253

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:44
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:03:09

FDA-CBER-2022-1614-0871254

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:44
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:03:09

FDA-CBER-2022-1614-0871255

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:44
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:03:09

FDA-CBER-2022-1614-0871256

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:44
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:03:09

FDA-CBER-2022-1614-0871257

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:44
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:03:09

FDA-CBER-2022-1614-0871258

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:44
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:03:09

FDA-CBER-2022-1614-0871259

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:44
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:03:09

FDA-CBER-2022-1614-0871260

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:44
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:03:09

FDA-CBER-2022-1614-0871261

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:44
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '06 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:03:09

FDA-CBER-2022-1614-0871262

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:44
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:03:09

FDA-CBER-2022-1614-0871263

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:44
User entered empty.	System	15 Mar 2021 16:03:09

FDA-CBER-2022-1614-0871264

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:44
User entered empty.	System	15 Mar 2021 16:03:09

FDA-CBER-2022-1614-0871265

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:44
User entered empty.	System	15 Mar 2021 16:03:09

FDA-CBER-2022-1614-0871266

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 16:06:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 16:06:58
Data point term sent to Coder	System	15 Mar 2021 16:06:27
User entered 'docusate'	(b) (4), (b) (6)	15 Mar 2021 16:06:24

FDA-CBER-2022-1614-0871267

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:06:24

FDA-CBER-2022-1614-0871268

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'constipation'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:06:24

FDA-CBER-2022-1614-0871269

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '100'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:06:24

FDA-CBER-2022-1614-0871270

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:06:24

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:06:24

FDA-CBER-2022-1614-0871272

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:06:24

FDA-CBER-2022-1614-0871273

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:06:24

FDA-CBER-2022-1614-0871274

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:06:24

FDA-CBER-2022-1614-0871275

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:06:24

FDA-CBER-2022-1614-0871276

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:06:24

FDA-CBER-2022-1614-0871277

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:06:24

FDA-CBER-2022-1614-0871278

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:06:24

FDA-CBER-2022-1614-0871279

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:06:24

FDA-CBER-2022-1614-0871280

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:06:24

FDA-CBER-2022-1614-0871281

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '2'	System	15 Mar 2021 16:06:24

FDA-CBER-2022-1614-0871282

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '1'	System	15 Mar 2021 16:06:24

FDA-CBER-2022-1614-0871283

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '804 (804)'	System	15 Mar 2021 16:06:24

FDA-CBER-2022-1614-0871284

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 10:01:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 10:01:49
Data point term sent to Coder	System	15 Mar 2021 16:11:39
User entered 'pantoprazole'	(b) (4), (b) (6)	15 Mar 2021 16:11:11

FDA-CBER-2022-1614-0871285

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:11:11

FDA-CBER-2022-1614-0871286

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'gastritis prophylaxis'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:11:11

FDA-CBER-2022-1614-0871287

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '40'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:11:11

FDA-CBER-2022-1614-0871288

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:11:11

FDA-CBER-2022-1614-0871289

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:11:11

FDA-CBER-2022-1614-0871290

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:11:11

FDA-CBER-2022-1614-0871291

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:11:11

FDA-CBER-2022-1614-0871292

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:11:11

FDA-CBER-2022-1614-0871293

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:11:11

FDA-CBER-2022-1614-0871294

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:11:11

FDA-CBER-2022-1614-0871295

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:11:11

FDA-CBER-2022-1614-0871296

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:11:11

FDA-CBER-2022-1614-0871297

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:11:11

FDA-CBER-2022-1614-0871298

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:11:11

FDA-CBER-2022-1614-0871299

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '1'	System	15 Mar 2021 16:11:11

FDA-CBER-2022-1614-0871300

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '1'	System	15 Mar 2021 16:11:11

FDA-CBER-2022-1614-0871301

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '804 (804)'	System	15 Mar 2021 16:11:11

FDA-CBER-2022-1614-0871302

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 16:15:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 16:15:57
Data point term sent to Coder	System	15 Mar 2021 16:13:43
User entered 'dexamethasone'	(b) (4), (b) (6)	15 Mar 2021 16:13:02

FDA-CBER-2022-1614-0871303

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:13:02

FDA-CBER-2022-1614-0871304

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'pneumonia'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:13:02

FDA-CBER-2022-1614-0871305

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '6'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:13:02

FDA-CBER-2022-1614-0871306

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:13:02

FDA-CBER-2022-1614-0871307

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:13:02

FDA-CBER-2022-1614-0871308

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:13:02

FDA-CBER-2022-1614-0871309

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:13:02

FDA-CBER-2022-1614-0871310

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:13:02

FDA-CBER-2022-1614-0871311

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:13:02

FDA-CBER-2022-1614-0871312

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:13:02

FDA-CBER-2022-1614-0871313

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:13:02

FDA-CBER-2022-1614-0871314

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:13:02

FDA-CBER-2022-1614-0871315

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:13:02

FDA-CBER-2022-1614-0871316

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:13:02

FDA-CBER-2022-1614-0871317

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:54
User entered '1'	System	15 Mar 2021 16:13:02

FDA-CBER-2022-1614-0871318

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:54
User entered '1'	System	15 Mar 2021 16:13:02

FDA-CBER-2022-1614-0871319

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:54
User entered '804 (804)'	System	15 Mar 2021 16:13:02

FDA-CBER-2022-1614-0871320

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 09:37:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 09:37:48
Data point term sent to Coder	System	15 Mar 2021 16:15:44
User entered 'dexamethasone'	(b) (4), (b) (6)	15 Mar 2021 16:14:45

FDA-CBER-2022-1614-0871321

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:14:45

FDA-CBER-2022-1614-0871322

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'pneumonia'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:14:45

FDA-CBER-2022-1614-0871323

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '6'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:14:45

FDA-CBER-2022-1614-0871324

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:14:45

FDA-CBER-2022-1614-0871325

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:14:45

FDA-CBER-2022-1614-0871326

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:14:45

FDA-CBER-2022-1614-0871327

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:14:45

FDA-CBER-2022-1614-0871328

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:14:45

FDA-CBER-2022-1614-0871329

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:14:45

FDA-CBER-2022-1614-0871330

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:14:45

FDA-CBER-2022-1614-0871331

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:14:45

FDA-CBER-2022-1614-0871332

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:14:45

FDA-CBER-2022-1614-0871333

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 06:24:05
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
Query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'CORRECT AS ENTERED. SUBJECT DIRECTED TO CONTINUE MEDICATION ALTHOUGH SYMPTOMS MAY HAVE RESOLVED.' (Site from DM).	Karol Moore (b) (4) (b) (4)	05 Apr 2021 18:38:55
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:07:50
User entered '28 Feb 2021'	(b) (4), (b) (6)	15 Mar 2021 16:14:45

FDA-CBER-2022-1614-0871334

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:14:45

FDA-CBER-2022-1614-0871335

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:57
User entered '1'	System	15 Mar 2021 16:14:45

FDA-CBER-2022-1614-0871336

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:57
User entered '1'	System	15 Mar 2021 16:14:45

FDA-CBER-2022-1614-0871337

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:07:57
User entered '804 (804)'	System	15 Mar 2021 16:14:45

FDA-CBER-2022-1614-0871338

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:08:00
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: ANTIVERTIGO PREPARATIONS, ATC: ANTIVERTIGO PREPARATIONS, PRODUCT: MECLOZINE, PRODUCTSYNONYM: MECLIZINE [MECLOZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 10:21:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 10:21:49
Data point term sent to Coder	System	15 Mar 2021 16:17:49
User entered 'meclizine'	(b) (4), (b) (6)	15 Mar 2021 16:17:07

FDA-CBER-2022-1614-0871339

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:08:00
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:17:07

FDA-CBER-2022-1614-0871340

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:08:00
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'aseptic meningitis'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:17:07

FDA-CBER-2022-1614-0871341

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:08:00
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '25'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:17:07

FDA-CBER-2022-1614-0871342

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:08:00
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:17:07

FDA-CBER-2022-1614-0871343

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:08:00
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:17:07

FDA-CBER-2022-1614-0871344

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:08:00
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:17:07

FDA-CBER-2022-1614-0871345

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:08:00
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:17:07

FDA-CBER-2022-1614-0871346

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:08:00
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:17:07

FDA-CBER-2022-1614-0871347

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:08:00
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:17:07

FDA-CBER-2022-1614-0871348

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:08:00
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:17:07

FDA-CBER-2022-1614-0871349

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:08:00
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:17:07

FDA-CBER-2022-1614-0871350

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:08:00
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:17:07

FDA-CBER-2022-1614-0871351

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:08:00
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:17:07

FDA-CBER-2022-1614-0871352

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:08:00
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:17:07

FDA-CBER-2022-1614-0871353

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:08:00
User entered empty.	System	15 Mar 2021 16:17:07

FDA-CBER-2022-1614-0871354

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:08:00
User entered empty.	System	15 Mar 2021 16:17:07

FDA-CBER-2022-1614-0871355

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:08:00
User entered empty.	System	15 Mar 2021 16:17:07

FDA-CBER-2022-1614-0871356

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 16:57:13
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 09:36:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 09:36:48
Data point term sent to Coder	System	15 Mar 2021 16:18:50
User entered 'cyclobenzaprine'	(b) (4), (b) (6)	15 Mar 2021 16:18:39

FDA-CBER-2022-1614-0871357

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 16:57:13
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 16:18:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 16:18:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 16:18:45
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 16:18:39
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 16:18:39

FDA-CBER-2022-1614-0871358

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 16:57:13
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'aseptic meningitis'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:18:39

FDA-CBER-2022-1614-0871359

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 16:57:13
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '5'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:18:39

FDA-CBER-2022-1614-0871360

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 16:57:13
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:18:39

FDA-CBER-2022-1614-0871361

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 16:57:13
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:18:39

FDA-CBER-2022-1614-0871362

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 16:57:13
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:18:39

FDA-CBER-2022-1614-0871363

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 16:57:13
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:18:39

FDA-CBER-2022-1614-0871364

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 16:57:13
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:18:39

FDA-CBER-2022-1614-0871365

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 16:57:13
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:18:39

FDA-CBER-2022-1614-0871366

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 16:57:13
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:18:39

FDA-CBER-2022-1614-0871367

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 16:57:13
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:18:39

FDA-CBER-2022-1614-0871368

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 16:57:13
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User closed query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 06:24:22
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:51:02
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'CONFIRMED STILL ONGOING PER SEQUELA OF AE' (Site from DM).	Karol Moore (b) (4) (b) (4)	05 Apr 2021 18:47:55
User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:08:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 16:18:39

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 16:57:13
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:18:39

FDA-CBER-2022-1614-0871370

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 16:57:13
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:51:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:18:39

FDA-CBER-2022-1614-0871371

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 16:57:13
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered empty.	System	15 Mar 2021 16:18:39

FDA-CBER-2022-1614-0871372

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered empty.	System	15 Mar 2021 16:18:39

FDA-CBER-2022-1614-0871373

US3312095
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 16:57:13
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered empty.	System	15 Mar 2021 16:18:39

FDA-CBER-2022-1614-0871374

US3312095
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 09 Jun 2021 16:57:13
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:02:41
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Apr 2021 19:42:41
Signature has been broken.	Karol Moore (b) (4) (b) (4)	09 Apr 2021 17:28:25
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	09 Apr 2021 17:28:25
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	08 Apr 2021 15:18:24
Signature has been broken.	Karol Moore (b) (4) (b) (4)	08 Apr 2021 14:31:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	08 Apr 2021 14:31:57
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'No (N)'	(b) (4), (b) (6)	18 Feb 2021 16:07:30

US3312095
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:57:13
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:46:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 15:12:32

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US3312095
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:57:13
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:45:12
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	22 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:33:56
User closed query 'Per CDM: per query response on the Concomitant medications page the off study vaccine was taken after the subject discontinued the study. Please update the reason for study discontinuation and the specify reason.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 03:26:12
Query 'Per CDM: per query response on the Concomitant medications page the off study vaccine was taken after the subject discontinued the study. Please update the reason for study discontinuation and the specify reason.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Apr 2021 16:04:41
DataPoint Un-verified.	Karol Moore (b) (4) (b) (4)	19 Apr 2021 16:04:19
Signature has been broken.	Karol Moore (b) (4) (b) (4)	19 Apr 2021 16:04:19
User entered 'Other (OTHER)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	19 Apr 2021 16:04:19
User opened query 'Per CDM: per query response on the Concomitant medications page the off study vaccine was taken after the subject discontinued the study. Please update the reason for study discontinuation and the specify reason.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 00:28:53
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:46:41
User closed query 'per CDM: per query response on conmed eCRF, subject received non-study EUA COVID vaccine after discontinuing from the study. If subject discontinued and then received EUA vaccine, it is not a protocol deviation. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 10:15:50

FDA-CBER-2022-1614-0871377

US3312095
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:57:13
Reason for discontinuation

Audit	User	Time (GMT)
Query 'per CDM: per query response on conmed eCRF, subject received non-study EUA COVID vaccine after discontinuing from the study. If subject discontinued and then received EUA vaccine, it is not a protocol deviation. Please review and reconcile.' answered with 'CORRECT AS ENTERED. PER SPONSOR FAQ, "PROTOCOL DEVIATION" ENTERED IN THIS SCENARIO FOR CONSISTENCY' (Site from DM).	Karol Moore (b) (4) (b) (4)	15 Apr 2021 18:59:41
User opened query 'per CDM: per query response on conmed eCRF, subject received non-study EUA COVID vaccine after discontinuing from the study. If subject discontinued and then received EUA vaccine, it is not a protocol deviation. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 18:34:30
User closed query 'Per CDM: per Sponsor review, per query response on ConMed eCRF - subject did not receive the non-study COVID vaccine until AFTER study discontinuation. In this case, it is not a protocol deviation. Please update reason for study discontinuation.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 05:10:23
Query 'Per CDM: per Sponsor review, per query response on ConMed eCRF - subject did not receive the non-study COVID vaccine until AFTER study discontinuation. In this case, it is not a protocol deviation. Please update reason for study discontinuation.' answered with 'CORRECT AS ENTERED. PER SPONSOR FAQ, "PROTOCOL DEVIATION" ENTERED IN THIS SCENARIO' (Site from DM).	Karol Moore (b) (4) (b) (4)	12 Apr 2021 19:23:37
User opened query 'Per CDM: per Sponsor review, per query response on ConMed eCRF - subject did not receive the non-study COVID vaccine until AFTER study discontinuation. In this case, it is not a protocol deviation. Please update reason for study discontinuation.' (Site from DM).	(b) (4), (b) (6)	11 Apr 2021 16:00:25

US3312095
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:57:13
Reason for discontinuation

Audit	User	Time (GMT)
Query 'Per CDM: Other is selected; however, options are present in the drop down that may be more appropriate. If subject was given other vaccine while on study please consider updating Other to PD and update CM form, If the subject Withdrew consent prior to taking other vaccine, please consider that option rather than Other' canceled (Site from DM).	(b) (4), (b) (6)	11 Apr 2021 16:00:18
User opened query 'Per CDM: Other is selected; however, options are present in the drop down that may be more appropriate. If subject was given other vaccine while on study please consider updating Other to PD and update CM form, If the subject Withdrew consent prior to taking other vaccine, please consider that option rather than Other' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 19:54:18
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	08 Apr 2021 15:18:24
User closed query 'Per CDM: per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:17:03
Query 'Per CDM: per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation.' answered with 'UPDATED' (Site from DM).	Monica Atwood (b) (4) (b) (4)	07 Apr 2021 17:40:07
Signature has been broken.	Monica Atwood (b) (4) (b) (4)	07 Apr 2021 17:39:45
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	07 Apr 2021 17:39:45
User opened query 'Per CDM: per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:32:14
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered 'Other (OTHER)'	(b) (4), (b) (6)	22 Mar 2021 15:12:32

FDA-CBER-2022-1614-0871379

US3312095

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:57:13

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:46:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
User entered 'COVID 19 EUA Vaccine outside of study'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 15:12:32

US3312095
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:57:13
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:46:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 15:12:32

FDA-CBER-2022-1614-0871381

US3312095
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:57:13
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:46:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 15:12:32

FDA-CBER-2022-1614-0871382

US3312095
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:57:13
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:46:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 15:12:32

FDA-CBER-2022-1614-0871383

US3312095
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:57:13
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:45:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:46:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 15:12:32

FDA-CBER-2022-1614-0871384

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'USA-US300-2020-MRNA-1273-P301000017'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871386

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871388

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871389

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871390

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'Carlos'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'Fierro'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871394

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered '16300 College Blvd'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871395

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'Shawnee'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871396

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'KS'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered '66219'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871398

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:07:43
User entered 'US'	System	08 Dec 2020 13:55:26

FDA-CBER-2022-1614-0871399

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '5'	System	26 Feb 2021 20:17:42
User entered '4'	System	05 Jan 2021 14:33:08
User entered '3'	System	30 Dec 2020 19:07:22
User entered '2'	System	23 Dec 2020 15:07:51
User entered '1'	System	08 Dec 2020 13:55:26

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'USA-US300-2020-MRNA-1273-P301000017'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871401

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871402

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871405

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871406

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871408

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'Carlos'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'Fierro'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871410

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered '16300 College Blvd'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871411

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'Shawnee'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871412

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'KS'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871413

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered '66219'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871414

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:07:43
User entered 'US'	System	08 Dec 2020 13:55:26

FDA-CBER-2022-1614-0871415

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '5'	System	26 Feb 2021 20:17:42
User entered '4'	System	05 Jan 2021 14:33:08
User entered '3'	System	30 Dec 2020 19:07:22
User entered '2'	System	23 Dec 2020 15:07:51
User entered '1'	System	08 Dec 2020 13:55:26

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form (1)
Generated On: 09 Jun 2021 16:57:13
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '08/Dec/2020 05:55'	System	08 Dec 2020 13:55:26

FDA-CBER-2022-1614-0871417

US3312095

Folder: SAE USA-US300-2020-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:57:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:07:43
User entered '1'	(b) (4), (b) (6)	08 Dec 2020 13:55:26

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'USA-US300-2020-MRNA-1273-P301000017'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871419

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871420

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871424

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871425

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871426

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'Carlos'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'Fierro'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871428

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered '16300 College Blvd'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871429

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'Shawnee'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871430

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'KS'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871431

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered '66219'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871432

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:07:43
User entered 'US'	System	08 Dec 2020 13:55:26

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '5'	System	26 Feb 2021 20:17:42
User entered '4'	System	05 Jan 2021 14:33:08
User entered '3'	System	30 Dec 2020 19:07:22
User entered '2'	System	23 Dec 2020 15:07:51
User entered '1'	System	08 Dec 2020 13:55:26

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 16:57:13
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '23/Dec/2020 15:07'	System	23 Dec 2020 15:07:51

FDA-CBER-2022-1614-0871435

US3312095

Folder: SAE USA-US300-2020-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:57:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 19:07:14
User entered '1'	(b) (4), (b) (6)	23 Dec 2020 15:07:51

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'USA-US300-2020-MRNA-1273-P301000017'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871437

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871438

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871441

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871442

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871443

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871444

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'Carlos'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871445

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'Fierro'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871446

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered '16300 College Blvd'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871447

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'Shawnee'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871448

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'KS'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871449

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered '66219'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871450

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:07:43
User entered 'US'	System	08 Dec 2020 13:55:26

FDA-CBER-2022-1614-0871451

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '5'	System	26 Feb 2021 20:17:42
User entered '4'	System	05 Jan 2021 14:33:08
User entered '3'	System	30 Dec 2020 19:07:22
User entered '2'	System	23 Dec 2020 15:07:51
User entered '1'	System	08 Dec 2020 13:55:26

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form (3)
Generated On: 09 Jun 2021 16:57:13
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '30/Dec/2020 14:07'	System	30 Dec 2020 19:07:22

US3312095

Folder: SAE USA-US300-2020-MRNA-1273-P301000017

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:57:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 19:08:00
User entered '1'	(b) (4), (b) (6)	30 Dec 2020 19:07:22

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'USA-US300-2020-MRNA-1273-P301000017'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871455

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871456

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871459

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871460

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871461

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'Carlos'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'Fierro'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871464

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered '16300 College Blvd'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871465

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'Shawnee'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871466

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'KS'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871467

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered '66219'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871468

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:07:43
User entered 'US'	System	08 Dec 2020 13:55:26

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '5'	System	26 Feb 2021 20:17:42
User entered '4'	System	05 Jan 2021 14:33:08
User entered '3'	System	30 Dec 2020 19:07:22
User entered '2'	System	23 Dec 2020 15:07:51
User entered '1'	System	08 Dec 2020 13:55:26

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form (4)
Generated On: 09 Jun 2021 16:57:13
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '05/Jan/2021 14:33'	System	05 Jan 2021 14:33:08

FDA-CBER-2022-1614-0871471

US3312095

Folder: SAE USA-US300-2020-MRNA-1273-P301000017

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:57:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
User entered '1'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:33:08

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'USA-US300-2020-MRNA-1273-P301000017'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871473

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871477

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871478

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871479

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'No (N)'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871480

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'Carlos'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871481

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'Fierro'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871482

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered '16300 College Blvd'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871483

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'Shawnee'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871484

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered 'KS'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871485

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:54:56
User entered '66219'	System	08 Dec 2020 13:53:39

FDA-CBER-2022-1614-0871486

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:07:43
User entered 'US'	System	08 Dec 2020 13:55:26

FDA-CBER-2022-1614-0871487

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '5'	System	26 Feb 2021 20:17:42
User entered '4'	System	05 Jan 2021 14:33:08
User entered '3'	System	30 Dec 2020 19:07:22
User entered '2'	System	23 Dec 2020 15:07:51
User entered '1'	System	08 Dec 2020 13:55:26

US3312095
Folder: SAE USA-US300-2020-MRNA-1273-P301000017
Form: Safety Report Form (5)
Generated On: 09 Jun 2021 16:57:13
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '26/Feb/2021 15:17'	System	26 Feb 2021 20:17:42

FDA-CBER-2022-1614-0871489

US3312095

Folder: SAE USA-US300-2020-MRNA-1273-P301000017

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:57:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
User entered '1'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:17:42

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 17:35:16
User entered 'USA-US300-2021-MRNA-1273-P301000019'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871491

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'Yes (Y)'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871492

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'No (N)'	System	24 Feb 2021 17:31:48

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'No (N)'	System	24 Feb 2021 17:31:48

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'Yes (Y)'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871495

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'No (N)'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871496

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'No (N)'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871497

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'No (N)'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871498

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'Carlos'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871499

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'Fierro'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871500

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered '16300 College Blvd'	System	24 Feb 2021 17:31:48

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'Shawnee'	System	24 Feb 2021 17:31:48

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'KS'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871503

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered '66219'	System	24 Feb 2021 17:31:48

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:51:35
User entered 'US'	System	24 Feb 2021 17:35:35

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '3'	System	19 Mar 2021 15:52:20
User entered '2'	System	11 Mar 2021 14:51:54
User entered '1'	System	24 Feb 2021 17:35:35

FDA-CBER-2022-1614-0871506

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:16
User entered 'USA-US300-2021-MRNA-1273-P301000019'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871507

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'Yes (Y)'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871508

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'No (N)'	System	24 Feb 2021 17:31:48

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'No (N)'	System	24 Feb 2021 17:31:48

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'Yes (Y)'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871511

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'No (N)'	System	24 Feb 2021 17:31:48

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'No (N)'	System	24 Feb 2021 17:31:48

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'No (N)'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871514

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'Carlos'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871515

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'Fierro'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871516

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered '16300 College Blvd'	System	24 Feb 2021 17:31:48

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'Shawnee'	System	24 Feb 2021 17:31:48

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'KS'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871519

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered '66219'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871520

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:51:35
User entered 'US'	System	24 Feb 2021 17:35:35

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '3'	System	19 Mar 2021 15:52:20
User entered '2'	System	11 Mar 2021 14:51:54
User entered '1'	System	24 Feb 2021 17:35:35

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form (1)
Generated On: 09 Jun 2021 16:57:13
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '24/Feb/2021 12:35'	System	24 Feb 2021 17:35:35

FDA-CBER-2022-1614-0871523

US3312095

Folder: SAE USA-US300-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:57:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:51:35
User entered '1'	(b) (4), (b) (6)	24 Feb 2021 17:35:35

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:16
User entered 'USA-US300-2021-MRNA-1273-P301000019'	System	24 Feb 2021 17:31:48

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'Yes (Y)'	System	24 Feb 2021 17:31:48

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'No (N)'	System	24 Feb 2021 17:31:48

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'No (N)'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871528

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'Yes (Y)'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871529

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'No (N)'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871530

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'No (N)'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871531

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'No (N)'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871532

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'Carlos'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871533

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'Fierro'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871534

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered '16300 College Blvd'	System	24 Feb 2021 17:31:48

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'Shawnee'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871536

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'KS'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871537

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered '66219'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871538

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:51:35
User entered 'US'	System	24 Feb 2021 17:35:35

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '3'	System	19 Mar 2021 15:52:20
User entered '2'	System	11 Mar 2021 14:51:54
User entered '1'	System	24 Feb 2021 17:35:35

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 16:57:13
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '11/Mar/2021 09:51'	System	11 Mar 2021 14:51:54

FDA-CBER-2022-1614-0871541

US3312095

Folder: SAE USA-US300-2021-MRNA-1273-P301000019

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:57:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
User entered '1'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:51:54

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:16
User entered 'USA-US300-2021-MRNA-1273-P301000019'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871543

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'Yes (Y)'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871544

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'No (N)'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871545

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'No (N)'	System	24 Feb 2021 17:31:48

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'Yes (Y)'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871547

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'No (N)'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871548

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'No (N)'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871549

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'No (N)'	System	24 Feb 2021 17:31:48

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'Carlos'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871551

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'Fierro'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871552

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered '16300 College Blvd'	System	24 Feb 2021 17:31:48

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'Shawnee'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871554

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered 'KS'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871555

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:22
User entered '66219'	System	24 Feb 2021 17:31:48

FDA-CBER-2022-1614-0871556

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:51:35
User entered 'US'	System	24 Feb 2021 17:35:35

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:57:13
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
User entered '3'	System	19 Mar 2021 15:52:20
User entered '2'	System	11 Mar 2021 14:51:54
User entered '1'	System	24 Feb 2021 17:35:35

FDA-CBER-2022-1614-0871558

US3312095
Folder: SAE USA-US300-2021-MRNA-1273-P301000019
Form: Safety Report Form (3)
Generated On: 09 Jun 2021 16:57:13
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:44:29
User entered '19/Mar/2021 08:52'	System	19 Mar 2021 15:52:20

FDA-CBER-2022-1614-0871559

US3312095

Folder: SAE USA-US300-2021-MRNA-1273-P301000019

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:57:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:44:29
User entered '1'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:52:20