US3242269 (Prod: Clinical Research Atlanta - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:13:41

All time stamps listed in this document are displayed in GMT

US3242269
Form: Participant Creation
Data signed: (b) (4) **12 Feb 2021 18:21:43**
Generated On: 09 Jun 2021 16:13:41

Participant ID	US3242269

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-0697721

US3242269
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-0697722

US3242269
Folder: Screening
Form: Demographics
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

Date of Birth (MMM yyyy)	(b) (6) 1942
Age	77
Age Units	YEARS
Age (Derived)	77
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-2022-1614-0697723

US3242269
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

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

FDA-CBER-2022-1614-0697724

US3242269
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

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

FDA-CBER-2022-1614-0697725

US3242269
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-0697726

US3242269
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	1 JAN 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0697727

US3242269
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	1 JAN 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0697728

US3242269
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Condition	SEASONAL ALLERGIC RHINITIS
Start date (dd MMM yyyy)	1 APR 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0697729

US3242269
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	1 JAN 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0697730

US3242269
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0697731

US3242269
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Condition	DIVERTICULOSIS
Start date (dd MMM yyyy)	10 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	20 JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

US3242269
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Condition	ASTHMA, EPISODIC
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0697733

US3242269
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	1 SEP 2020
Time of assessment *(00:00-23:59)*	11:28 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 11:28
Height *(xxx.x)*	68 in
Weight *(xxx.x)*	165 lb
BMI *(xxx.x)*	25.14062 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-2022-1614-0697734

US3242269
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

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

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

FDA-CBER-2022-1614-0697735

US3242269
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

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	RETIRED, SHOPS IN THE COMMUNITY SEVERAL TIMES A WEEK

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

US3242269
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

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

US3242269
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	1 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-0697738

US3242269
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

What was the date of randomization? *(dd MMM yyyy)*	01 SEP 2020
What was the participant's randomization number?	189359
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-2022-1614-0697739

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-0697740

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

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)*	1 SEP 2020
Time of assessment *(00:00-23:59)*	11:45 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 11:45
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	76 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0697741

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

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)*	1 SEP 2020
Time of assessment *(00:00-23:59)*	13:14 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 13:14
Temperature *(xxx.x)*	97.9 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	72 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0697742

US3242269
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

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-2022-1614-0697743

US3242269
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	1 SEP 2020
What was the treatment time? *(00:00-23:59)*	12:44 (24 HR)
Treatment Date and Time (derived)	1 SEP 2020 12:44
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-2022-1614-0697744

US3242269
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	1 SEP 2020
Collection time *(00:00-23:59)*	12:30 (24 HR)
Collection date and time (derived)	1 SEP 2020 12:30

FDA-CBER-2022-1614-0697745

US3242269
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Collection date *(dd MMM yyyy)*			1 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:25	1 SEP 2020 12:25
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0697746

US3242269
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

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

FDA-CBER-2022-1614-0697747

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**	97.9 °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	01 SEP 2020 13:23
PC Open Date & Time	01 SEP 2020 13:04
PC Close Date & Time	01 SEP 2020 15:34

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	01 SEP 2020 18:27
PC Open Date & Time	01 SEP 2020 16:29
PC Close Date & Time	02 SEP 2020 11:59

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:13:41

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	02 SEP 2020 19:36
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:13:41

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**	98.8 °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	03 SEP 2020 19:10
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:13:41

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**	98.6 °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	04 SEP 2020 19:24
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	05 SEP 2020 19:09
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:13:41

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**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	06 SEP 2020 20:45
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:13:41

TIMEPOINT	DAY 7

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

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

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

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

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

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

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

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:13:41

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	01 SEP 2020 13:24
PC Open Date & Time	01 SEP 2020 13:04
PC Close Date & Time	01 SEP 2020 15:34

FDA-CBER-2022-1614-0697756

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:13:41

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	01 SEP 2020 18:29
PC Open Date & Time	01 SEP 2020 16:29
PC Close Date & Time	02 SEP 2020 11:59

FDA-CBER-2022-1614-0697757

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:13:41

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	02 SEP 2020 19:37
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

FDA-CBER-2022-1614-0697758

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:13:41

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	03 SEP 2020 19:11
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-0697759

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:13:41

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	04 SEP 2020 19:25
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

FDA-CBER-2022-1614-0697760

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:13:41

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	05 SEP 2020 19:10
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-0697761

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:13:41

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	06 SEP 2020 20:45
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

FDA-CBER-2022-1614-0697762

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:13:41

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	_____
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	_____
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	_____
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

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 ☐

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	01 SEP 2020 13:25
PC Open Date & Time	01 SEP 2020 13:04
PC Close Date & Time	01 SEP 2020 15:34

FDA-CBER-2022-1614-0697765

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 ☐

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	01 SEP 2020 18:31
PC Open Date & Time	01 SEP 2020 16:29
PC Close Date & Time	02 SEP 2020 11:59

FDA-CBER-2022-1614-0697767

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41

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-2022-1614-0697768

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41

	Yes
PC Time stamp	02 SEP 2020 19:39
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

FDA-CBER-2022-1614-0697769

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 ■

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41

	Yes
PC Time stamp	03 SEP 2020 19:13
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-0697771

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 ■

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41

	Yes
PC Time stamp	04 SEP 2020 19:27
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 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 ■

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41

	Yes
PC Time stamp	05 SEP 2020 19:12
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-0697775

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 ■

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41

	Yes
PC Time stamp	06 SEP 2020 20:46
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

FDA-CBER-2022-1614-0697777

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 ☐

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

US3242269
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	8 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3242269
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

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

FDA-CBER-2022-1614-0697781

US3242269
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

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

US3242269
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

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

FDA-CBER-2022-1614-0697783

US3242269
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	23 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-2022-1614-0697784

US3242269
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

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

FDA-CBER-2022-1614-0697785

US3242269
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-0697786

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	30 SEP 2020
Time of assessment *(00:00-23:59)*	11:03 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 11:03
Temperature *(xxx.x)*	97.6 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	92 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	50 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0697787

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	30 SEP 2020
Time of assessment *(00:00-23:59)*	12:50 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 12:50
Temperature *(xxx.x)*	97.3 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	88 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	62 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0697788

US3242269
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

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-2022-1614-0697789

US3242269
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	30 SEP 2020
What was the treatment time? *(00:00-23:59)*	12:15 (24 HR)
Treatment Date and Time (derived)	30 SEP 2020 12:15
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-2022-1614-0697790

US3242269
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	30 SEP 2020
Collection time *(00:00-23:59)*	11:53 (24 HR)
Collection date and time (derived)	30 SEP 2020 11:53

US3242269
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Collection date *(dd MMM yyyy)*			30 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:45	30 SEP 2020 11:45
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0697792

US3242269
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

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

FDA-CBER-2022-1614-0697793

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:13:41

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**	97.8 °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	30 SEP 2020 12:48
PC Open Date & Time	30 SEP 2020 12:35
PC Close Date & Time	30 SEP 2020 15:05

FDA-CBER-2022-1614-0697794

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**	98.9 °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	30 SEP 2020 16:05
PC Open Date & Time	30 SEP 2020 16:00
PC Close Date & Time	01 OCT 2020 11:59

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:13:41

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**	98.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	01 OCT 2020 19:59
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:13:41

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**	98.7 °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	03 OCT 2020 11:27
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:13:41

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**	97.8 °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	03 OCT 2020 19:03
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:13:41

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	04 OCT 2020 18:01
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:13:41

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.8 °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	05 OCT 2020 19:43
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:13:41

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	06 OCT 2020 17:53
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:13:41

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	30 SEP 2020 12:50
PC Open Date & Time	30 SEP 2020 12:35
PC Close Date & Time	30 SEP 2020 15:05

FDA-CBER-2022-1614-0697802

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:13:41

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	30 SEP 2020 16:07
PC Open Date & Time	30 SEP 2020 16:00
PC Close Date & Time	01 OCT 2020 11:59

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:13:41

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	01 OCT 2020 20:01
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

FDA-CBER-2022-1614-0697804

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:13:41

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	03 OCT 2020 11:28
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:13:41

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	03 OCT 2020 19:04
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:13:41

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	04 OCT 2020 18:02
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:13:41

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	05 OCT 2020 19:44
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:13:41

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	06 OCT 2020 17:54
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

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

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	30 SEP 2020 12:51
PC Open Date & Time	30 SEP 2020 12:35
PC Close Date & Time	30 SEP 2020 15:05

FDA-CBER-2022-1614-0697811

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 ☐

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	30 SEP 2020 16:08
PC Open Date & Time	30 SEP 2020 16:00
PC Close Date & Time	01 OCT 2020 11:59

FDA-CBER-2022-1614-0697813

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 ■

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41

	Yes
PC Time stamp	01 OCT 2020 20:02
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

FDA-CBER-2022-1614-0697815

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41

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-2022-1614-0697816

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41

	Yes
PC Time stamp	03 OCT 2020 11:29
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

FDA-CBER-2022-1614-0697817

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 ■

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41

	Yes
PC Time stamp	03 OCT 2020 19:05
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

FDA-CBER-2022-1614-0697819

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41

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 ■

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41

	Yes
PC Time stamp	04 OCT 2020 18:03
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

FDA-CBER-2022-1614-0697821

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41

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-2022-1614-0697822

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41

	Yes
PC Time stamp	05 OCT 2020 19:45
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

FDA-CBER-2022-1614-0697823

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41

TIMEPOINT	DAY 7
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-0697824

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41

	Yes
PC Time stamp	06 OCT 2020 17:55
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

FDA-CBER-2022-1614-0697825

US3242269
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	7 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-2022-1614-0697826

US3242269
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

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

FDA-CBER-2022-1614-0697827

US3242269
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	14 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-2022-1614-0697828

US3242269
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

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

FDA-CBER-2022-1614-0697829

US3242269
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	21 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-2022-1614-0697830

US3242269
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

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

FDA-CBER-2022-1614-0697831

US3242269
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ■ Clinic ☐
Folder OID	VISIT3

FDA-CBER-2022-1614-0697832

US3242269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **12 Feb 2021 18:22:05**
Generated On: 09 Jun 2021 16:13:41

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	28 OCT 2020
Time of assessment *(00:00-23:59)*	11:25 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 11:25
Temperature *(xxx.x)*	97.1 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0697833

US3242269
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

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-2022-1614-0697834

US3242269
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	28 OCT 2020
Collection time *(00:00-23:59)*	12:05 (24 HR)
Collection date and time (derived)	28 OCT 2020 12:05

FDA-CBER-2022-1614-0697835

US3242269
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:21:45**
Generated On: 09 Jun 2021 16:13:41

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

FDA-CBER-2022-1614-0697836

US3242269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Date and time of submission	01 NOV 2020 08:08:23
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3242269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 NOV 2020 19:52:47
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

FDA-CBER-2022-1614-0697838

US3242269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41

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	15 NOV 2020 16:16:50
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

FDA-CBER-2022-1614-0697839

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 04:00:38
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

FDA-CBER-2022-1614-0697840

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 13:30:48
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

FDA-CBER-2022-1614-0697841

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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	06 DEC 2020 17:42:48
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

FDA-CBER-2022-1614-0697842

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 04:02:06
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

FDA-CBER-2022-1614-0697843

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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	19 DEC 2020 03:02:29
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

FDA-CBER-2022-1614-0697844

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41

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	26 DEC 2020 06:42:20
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

FDA-CBER-2022-1614-0697845

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41

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	02 JAN 2021 12:18:33
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

FDA-CBER-2022-1614-0697846

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

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41

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

FDA-CBER-2022-1614-0697848

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have 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	15 JAN 2021 17:29:07
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

FDA-CBER-2022-1614-0697849

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

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41

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

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission

US3242269
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	23 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-2022-1614-0697853

US3242269
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

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

FDA-CBER-2022-1614-0697854

US3242269
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

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

FDA-CBER-2022-1614-0697855

US3242269
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

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

FDA-CBER-2022-1614-0697856

US3242269
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41

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

FDA-CBER-2022-1614-0697857

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

US3242269
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 16:13:41

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

FDA-CBER-2022-1614-0697859

US3242269
Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Generated On: 09 Jun 2021 16:13:41

Generate Next COVID-19 Assessment	Yes ☐ No ☐

FDA-CBER-2022-1614-0697860

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	22 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ■ Clinic ☐
Folder OID	UNBLND_DECIDE

FDA-CBER-2022-1614-0697861

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **15 Mar 2021 16:07:32**
Generated On: 09 Jun 2021 16:13:41

Date of updated informed consent *(dd MMM yyyy)*	22 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ■ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ■
Date of unblinding *(dd MMM yyyy)*	22 JAN 2021
Participant randomization assignment	mRNA-1273 ■ Placebo ☐
Actual Dose 1	mRNA-1273 ■ Placebo ☐ Not Administered ☐
Actual Dose 2	mRNA-1273 ■ Placebo ☐ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☐ No ■
Placebo Only Flag	
Continuing with mRNA-1273	

FDA-CBER-2022-1614-0697862

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

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

FDA-CBER-2022-1614-0697863

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

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

US3242269
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **12 Feb 2021 18:21:43**
Generated On: 09 Jun 2021 16:13:41

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

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-0697865

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **22 Feb 2021 13:55:31**
Generated On: 09 Jun 2021 16:13:41

AEID	
Adverse event	CLOSED FRACTURE OF BASE OF 5TH METATARSAL BONE, LEFT FOOT
Was this a medically-attended AE?	Yes ■ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ■
Start date *(dd MMM yyyy)*	2 OCT 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	02 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ■ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ■ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **22 Feb 2021 13:55:31**
Generated On: 09 Jun 2021 16:13:41

AEID	
Adverse event	ASTHMA EXACERBATION
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)*	15 OCT 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	07 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 ☐
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ■ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Data signed: (b) (4) **22 Feb 2021 13:55:31**
Generated On: 09 Jun 2021 16:13:41

AEID	
Adverse event	ACUTE FRONTAL SINUSITIS
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)*	29 OCT 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	06 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ■ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ■ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Data signed: (b) (4) **22 Feb 2021 13:55:31**
Generated On: 09 Jun 2021 16:13:41

AEID	USA-US067-2020-MRNA-1273-P30 1000019
Adverse event	HEPATOCELLULAR CARCINOMA
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)*	07 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)*	
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	True
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

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

Narrative

	SUBJECT REPORTED IN E-DIARY THAT HE HAD CONTACT WITH A MEDICAL PROVIDER. SUBJECT RECEIVED LIVER BIOPSY. MEDICAL RECORDS RECEIVED AND REVIEWED WITH DIAGNOSIS FOR HEPATOCELLULAR CARCINOMA. WILL FOLLOW SUBJECT FOR PLAN OF TREATMENT. SUBJECT WITHDREW CONSENT, AE ONGOING AT TIME OF WITHDRAWAL.
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)	

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

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

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

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **12 Feb 2021 18:21:43**
Generated On: 09 Jun 2021 16:13:41

Name of Medication	FLECAINIDE ACETATE
Prophylaxis	Yes ☐ No ■
Indication	ATRIAL FIBRILLATION
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 ☐

	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 2011
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 ■

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **12 Feb 2021 18:21:43**
Generated On: 09 Jun 2021 16:13:41

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

FDA-CBER-2022-1614-0697878

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 MAY 2018
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **12 Feb 2021 18:21:43**
Generated On: 09 Jun 2021 16:13:41

Name of Medication	DILTIAZEM
Prophylaxis	Yes ☐ No ■
Indication	HYPERTENSION
Dose per administration	180
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	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)*	1 JAN 2010
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 ■

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **12 Feb 2021 18:21:43**
Generated On: 09 Jun 2021 16:13:41

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

FDA-CBER-2022-1614-0697882

	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)*	1 JAN 2010
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 ■

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **12 Feb 2021 18:21:43**
Generated On: 09 Jun 2021 16:13:41

Name of Medication	PANTOPRAZOLE
Prophylaxis	Yes ☐ No ■
Indication	GASTROESOPHAGEAL REFLUX DISEASE
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 ☐
	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)*	1 JAN 2017
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **12 Feb 2021 18:21:43**
Generated On: 09 Jun 2021 16:13:41

Name of Medication	LEVOCETIRIZINE DIHYDROCHLORIDE
Prophylaxis	Yes ☐ No ■
Indication	SEASONAL ALLERGIC RHINITIS
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 ☐

FDA-CBER-2022-1614-0697886

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

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **12 Feb 2021 18:21:43**
Generated On: 09 Jun 2021 16:13:41

Name of Medication	FLONASE
Prophylaxis	Yes ☐ No ■
Indication	ASTHMA EXACERBATION
Dose per administration	50
Dose unit	mg ☐ ug ■ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ■ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	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 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	30 OCT 2020
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 ■

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **12 Feb 2021 18:21:43**
Generated On: 09 Jun 2021 16:13:41

Name of Medication	PREDNISONE
Prophylaxis	Yes ☐ No ■
Indication	ASTHMA EXACERBATION
Dose per administration	4
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ■
If frequency is Other, specify	AS DIRECTED
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 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	28 OCT 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **12 Feb 2021 18:21:43**
Generated On: 09 Jun 2021 16:13:41

Name of Medication	MUCINEX
Prophylaxis	Yes ☐ No ■
Indication	ASTHMA EXACERBATION
Dose per administration	1200
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 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	28 OCT 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **12 Feb 2021 18:21:43**
Generated On: 09 Jun 2021 16:13:41

Name of Medication	ALBUTEROL
Prophylaxis	Yes ○ No ●
Indication	ASTHMA EXACERBATION
Dose per administration	90
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-2022-1614-0697894

	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 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	07 DEC 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 ☐

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Data signed: (b) (4) **12 Feb 2021 18:21:43**
Generated On: 09 Jun 2021 16:13:41

Name of Medication	DECADRON
Prophylaxis	Yes ☐ No ■
Indication	ACUTE FRONTAL SINUSITIS
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 ☐ Intraocular ☐

	Intramuscular ■ Respiratory (Inhalation) ☐ Intralesional ☐ Intraperiteoneal ☐ Nasal ☐ Vaginal ☐ Rectal ☐ Intravenous ☐ Intravenous Bolus ☐ Intravenous Drip ☐ Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	31 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	31 OCT 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Data signed: (b) (4) **12 Feb 2021 18:21:43**
Generated On: 09 Jun 2021 16:13:41

Name of Medication	ROCEPHIN
Prophylaxis	Yes ☐ No ■
Indication	ACUTE FRONTAL SINUSITIS
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)*	31 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	31 OCT 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Data signed: (b) (4) **12 Feb 2021 18:21:43**
Generated On: 09 Jun 2021 16:13:41

Name of Medication	AUGMENTIN
Prophylaxis	Yes ☐ No ■
Indication	ACUTE FRONTAL SINUSITIS
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)*	31 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	11 NOV 2020
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 ■

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Data signed: (b) (4) **12 Feb 2021 18:21:43**
Generated On: 09 Jun 2021 16:13:41

Name of Medication	BROMFED DM
Prophylaxis	Yes No ■
Indication	ACUTE FRONTAL SINUSITIS
Dose per administration	30/2/10
Dose unit	mg ■ ug mL g IU tablet capsule puff Other
If dose unit is Other, specify	
Frequency	once daily twice daily three times daily four times daily every other day every week every month as needed once unknown other ■
If frequency is Other, specify	EVERY 6 HOURS
Route of administration	Oral ■ Topical Subcutaneous Transdermal Intraocular

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	31 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	06 NOV 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Data signed: (b) (4) **12 Feb 2021 18:21:43**
Generated On: 09 Jun 2021 16:13:41

Name of Medication	ZITHROMAX
Prophylaxis	Yes ☐ No ■
Indication	ACUTE FRONTAL SINUSITIS
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 ☐

	Intramuscular ☐ Respiratory (Inhalation) ☐ Intralesional ☐ Intraperiteoneal ☐ Nasal ☐ Vaginal ☐ Rectal ☐ Intravenous ☐ Intravenous Bolus ☐ Intravenous Drip ☐ Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	31 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	31 OCT 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Data signed: (b) (4) **12 Feb 2021 18:21:43**
Generated On: 09 Jun 2021 16:13:41

Name of Medication	ZITHROMAX
Prophylaxis	Yes ○ No ●
Indication	ACUTE FRONTAL SINUSITIS
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)*	01 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	04 NOV 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3242269
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

Were any concomitant procedures performed? Yes ☒ No ☐

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-0697908

US3242269
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures
Data signed: (b) (4) **12 Feb 2021 18:21:44**
Generated On: 09 Jun 2021 16:13:41

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
03 DEC 2020	LIVER BIOPSY	Adverse Event	

FDA-CBER-2022-1614-0697909

US3242269
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **20 Apr 2021 21:22:29**
Generated On: 09 Jun 2021 16:13:41

Date of study discontinuation/completion *(dd MMM yyyy)*	22 JAN 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	MOVED IN WITH SON, TO FAR AWAY TO PARTICIPATE
If reason for discontinuation is Death, main cause of death	Adverse event ☐ Unknown ☐ Other ☐
If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	
Was autopsy performed?	Yes ☐ No ☐ Unknown ☐

FDA-CBER-2022-1614-0697910

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Data signed: (b) (4) **08 Apr 2021 21:17:50**
Generated On: 09 Jun 2021 16:13:41

SAEID	USA-US067-2020-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	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form (1)
Data signed: (b) (4) **08 Apr 2021 21:17:50**
Generated On: 09 Jun 2021 16:13:41

SAEID	USA-US067-2020-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	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	15/DEC/2020 13:58
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

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form (2)
Data signed: (b) (4) **08 Apr 2021 21:17:50**
Generated On: 09 Jun 2021 16:13:41

SAEID	USA-US067-2020-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	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/FEB/2021 13:25
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

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form (3)
Data signed: (b) (4) **08 Apr 2021 21:17:50**
Generated On: 09 Jun 2021 16:13:41

SAEID	USA-US067-2020-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	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/FEB/2021 14:48
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

US3242269 (Prod: Clinical Research Atlanta - ERN-PPDS)

US3242269
Form: Participant Creation
Generated On: 09 Jun 2021 16:13:41
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:53:40
User entered 'US3242269'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:54:42

FDA-CBER-2022-1614-0697916

US3242269
Form: Participant Creation
Generated On: 09 Jun 2021 16:13:41

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0697917

US3242269
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:13:41
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:54:14
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:22:52

FDA-CBER-2022-1614-0697918

US3242269
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:13:41
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:54:18
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:54:43

FDA-CBER-2022-1614-0697919

US3242269
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:13:41
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:54:20
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	01 Sep 2020 16:22:52

FDA-CBER-2022-1614-0697920

US3242269
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:13:41
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
User entered 'SCRN'	System	01 Sep 2020 16:22:52

FDA-CBER-2022-1614-0697921

US3242269
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:13:41
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:54:58
User entered (b) (6) 1942'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:54:44

FDA-CBER-2022-1614-0697922

US3242269
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:13:41
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:54:58
User entered '77'	Donna Toepfer (b) (4)	01 Sep 2020 16:23:16

FDA-CBER-2022-1614-0697923

US3242269
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:13:41
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'YEARS'	(b) (4), (b) (6) System	01 Sep 2020 16:23:16

FDA-CBER-2022-1614-0697924

US3242269
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:13:41
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '77'	(b) (4), (b) (6) System	01 Sep 2020 16:23:37

FDA-CBER-2022-1614-0697925

US3242269
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:13:41
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:54:58
User entered 'Male (M)'	Donna Toepfer (b) (4)	01 Sep 2020 16:23:16

FDA-CBER-2022-1614-0697926

US3242269
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:13:41
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:54:58
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Donna Toepfer (b) (4)	01 Sep 2020 16:23:16

FDA-CBER-2022-1614-0697927

US3242269
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:13:41
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:54:58
User entered '1'	Donna Toepfer (b) (4)	01 Sep 2020 16:23:16

FDA-CBER-2022-1614-0697928

US3242269
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:13:41
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:54:58
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:23:16

FDA-CBER-2022-1614-0697929

US3242269
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:13:41
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:54:58
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:23:16

FDA-CBER-2022-1614-0697930

US3242269
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:13:41
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:54:58
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:23:16

FDA-CBER-2022-1614-0697931

US3242269
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:13:41
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:54:58
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:23:16

FDA-CBER-2022-1614-0697932

US3242269
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:13:41
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:54:58
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:23:16

FDA-CBER-2022-1614-0697933

US3242269
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:13:41
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:54:58
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:23:16

FDA-CBER-2022-1614-0697934

US3242269
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:13:41
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:54:58
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:23:16

FDA-CBER-2022-1614-0697935

US3242269
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:13:41
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:54:58
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:23:16

FDA-CBER-2022-1614-0697936

US3242269
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:13:41
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:56:03
User entered '1 Sep 2020'	Donna Toepfer (b) (4)	01 Sep 2020 16:23:37

FDA-CBER-2022-1614-0697937

US3242269
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:13:41
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'Sep 2020'	(b) (4), (b) (6) System	01 Sep 2020 16:23:37

FDA-CBER-2022-1614-0697938

US3242269
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:13:41
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '2020'	(b) (4), (b) (6) System	01 Sep 2020 16:23:37

FDA-CBER-2022-1614-0697939

US3242269
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:13:41
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:56:03
User entered 'Amendment 3 (3)'	Donna Toepfer (b) (4)	01 Sep 2020 16:23:37

FDA-CBER-2022-1614-0697940

US3242269
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:13:41
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:56:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:23:37

FDA-CBER-2022-1614-0697941

US3242269
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:13:41
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:56:03
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:23:37

FDA-CBER-2022-1614-0697942

US3242269
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:13:41
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:56:03
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:23:37

FDA-CBER-2022-1614-0697943

US3242269
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:13:41
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:56:03
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:23:37

FDA-CBER-2022-1614-0697944

US3242269
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:13:41
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:56:03
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:54:43

FDA-CBER-2022-1614-0697945

US3242269
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:13:41
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	01 Sep 2020 16:23:41

FDA-CBER-2022-1614-0697946

US3242269
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 09 Jun 2021 16:13:41
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:56:39
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:23:41

FDA-CBER-2022-1614-0697947

US3242269
Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 16:13:41
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 19:57:23
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:23:46

FDA-CBER-2022-1614-0697948

US3242269
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:13:41
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:26:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:26:50
Data point term sent to Coder	System	01 Sep 2020 16:25:22
User entered 'Atrial Fibrillation'	Donna Toepfer (b) (4)	01 Sep 2020 16:24:22

FDA-CBER-2022-1614-0697949

US3242269
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:13:41
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered '1 Jan 2011'	Donna Toepfer (b) (4)	01 Sep 2020 16:24:22

FDA-CBER-2022-1614-0697950

US3242269
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:24:22

FDA-CBER-2022-1614-0697951

US3242269
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:13:41
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:24:22

FDA-CBER-2022-1614-0697952

US3242269
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:13:41
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:24:22

FDA-CBER-2022-1614-0697953

US3242269
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:13:41
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:24:22

FDA-CBER-2022-1614-0697954

US3242269
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:13:41
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'Jan 2011'	(b) (4), (b) (6) System	01 Sep 2020 16:24:22

FDA-CBER-2022-1614-0697955

US3242269
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:13:41
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '2011'	(b) (4), (b) (6) System	01 Sep 2020 16:24:22

FDA-CBER-2022-1614-0697956

US3242269
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:13:41
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	01 Sep 2020 16:24:22

FDA-CBER-2022-1614-0697957

US3242269
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:13:41
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	01 Sep 2020 16:24:22

FDA-CBER-2022-1614-0697958

US3242269
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:13:41
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:26:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:26:49
Data point term sent to Coder	System	01 Sep 2020 16:25:22
User entered 'Gastroesophageal reflux disease'	Donna Toepfer (b) (4)	01 Sep 2020 16:24:37

FDA-CBER-2022-1614-0697959

US3242269
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:13:41
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered '1 Jan 2017'	Donna Toepfer (b) (4)	01 Sep 2020 16:24:37

FDA-CBER-2022-1614-0697960

US3242269
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:24:37

FDA-CBER-2022-1614-0697961

US3242269
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:13:41
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:24:37

FDA-CBER-2022-1614-0697962

US3242269
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:13:41
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:24:37

FDA-CBER-2022-1614-0697963

US3242269
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:13:41
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:24:37

FDA-CBER-2022-1614-0697964

US3242269
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:13:41
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'Jan 2017'	(b) (4), (b) (6) System	01 Sep 2020 16:24:37

FDA-CBER-2022-1614-0697965

US3242269
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:13:41
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '2017'	(b) (4), (b) (6) System	01 Sep 2020 16:24:37

FDA-CBER-2022-1614-0697966

US3242269
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:13:41
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	01 Sep 2020 16:24:37

FDA-CBER-2022-1614-0697967

US3242269
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:13:41
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	01 Sep 2020 16:24:37

FDA-CBER-2022-1614-0697968

US3242269
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:13:41
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:26:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:26:48
Data point term sent to Coder	System	01 Sep 2020 16:25:25
User entered 'Seasonal allergic rhinitis'	Donna Toepfer (b) (4)	01 Sep 2020 16:24:49

FDA-CBER-2022-1614-0697969

US3242269
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:13:41
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered '1 Apr 2018'	Donna Toepfer (b) (4)	01 Sep 2020 16:24:49

FDA-CBER-2022-1614-0697970

US3242269
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:24:49

FDA-CBER-2022-1614-0697971

US3242269
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:13:41
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:24:49

FDA-CBER-2022-1614-0697972

US3242269
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:13:41
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:24:49

FDA-CBER-2022-1614-0697973

US3242269
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:13:41
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:24:49

FDA-CBER-2022-1614-0697974

US3242269
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:13:41
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'Apr 2018'	(b) (4), (b) (6) System	01 Sep 2020 16:24:49

FDA-CBER-2022-1614-0697975

US3242269
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:13:41
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '2018'	(b) (4), (b) (6) System	01 Sep 2020 16:24:49

FDA-CBER-2022-1614-0697976

US3242269
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:13:41
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	01 Sep 2020 16:24:49

FDA-CBER-2022-1614-0697977

US3242269
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:13:41
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	01 Sep 2020 16:24:49

FDA-CBER-2022-1614-0697978

US3242269
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:13:41
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:26:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:26:49
Data point term sent to Coder	System	01 Sep 2020 16:25:24
User entered 'Hypercholesterolemia'	Donna Toepfer (b) (4)	01 Sep 2020 16:25:01

FDA-CBER-2022-1614-0697979

US3242269
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:13:41
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered '1 Jan 2008'	Donna Toepfer (b) (4)	01 Sep 2020 16:25:01

FDA-CBER-2022-1614-0697980

US3242269
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:25:01

FDA-CBER-2022-1614-0697981

US3242269
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:13:41
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:25:01

FDA-CBER-2022-1614-0697982

US3242269
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:13:41
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:25:01

FDA-CBER-2022-1614-0697983

US3242269
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:13:41
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:25:01

FDA-CBER-2022-1614-0697984

US3242269
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:13:41
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'Jan 2008'	(b) (4), (b) (6) System	01 Sep 2020 16:25:01

FDA-CBER-2022-1614-0697985

US3242269
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:13:41
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '2008'	(b) (4), (b) (6) System	01 Sep 2020 16:25:01

FDA-CBER-2022-1614-0697986

US3242269
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:13:41
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	01 Sep 2020 16:25:01

FDA-CBER-2022-1614-0697987

US3242269
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:13:41
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	01 Sep 2020 16:25:01

FDA-CBER-2022-1614-0697988

US3242269
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:13:41
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:26:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:26:50
Data point term sent to Coder	System	01 Sep 2020 16:26:27
User entered 'Hypertension'	Donna Toepfer (b) (4)	01 Sep 2020 16:25:31

FDA-CBER-2022-1614-0697989

US3242269
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:13:41
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered 'Un UNK 2010'	Donna Toepfer (b) (4)	01 Sep 2020 16:25:31

FDA-CBER-2022-1614-0697990

US3242269
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:25:31

FDA-CBER-2022-1614-0697991

US3242269
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:13:41
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:25:31

FDA-CBER-2022-1614-0697992

US3242269
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:13:41
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:25:31

FDA-CBER-2022-1614-0697993

US3242269
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:13:41
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:14
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:25:31

FDA-CBER-2022-1614-0697994

US3242269
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:13:41
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'Jan 2010'	(b) (4), (b) (6) System	01 Sep 2020 16:25:31

FDA-CBER-2022-1614-0697995

US3242269
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:13:41
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '2010'	(b) (4), (b) (6) System	01 Sep 2020 16:25:31

FDA-CBER-2022-1614-0697996

US3242269
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:13:41
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	01 Sep 2020 16:25:31

FDA-CBER-2022-1614-0697997

US3242269
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:13:41
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	01 Sep 2020 16:25:31

FDA-CBER-2022-1614-0697998

US3242269
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:13:41
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:02
User coded data point as SOC: Gastrointestinal disorders, HLGT: Diverticular disorders, HLT: Diverticula, PT: Diverticulum, LLT: Diverticulosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Dec 2020 15:45:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Dec 2020 15:45:02
Data point term sent to Coder	System	05 Dec 2020 15:43:24
User entered 'Diverticulosis'	Donna Toepfer (b) (4)	05 Dec 2020 15:43:19

FDA-CBER-2022-1614-0697999

US3242269
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:13:41
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:02
User entered '10 Jul 2020'	Donna Toepfer (b) (4)	05 Dec 2020 15:43:19

FDA-CBER-2022-1614-0698000

US3242269
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:02
User entered '0'	Donna Toepfer (b) (4)	05 Dec 2020 15:43:19

FDA-CBER-2022-1614-0698001

US3242269
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:13:41
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:02
User entered 'No (N)' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	16 Dec 2020 19:02:51
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	05 Dec 2020 15:43:19

US3242269
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:13:41
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:02
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	16 Dec 2020 19:20:32
User entered '20 Jul 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Dec 2020 19:20:32
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	16 Dec 2020 19:02:51
User entered '20 Jul 2029' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	16 Dec 2020 19:02:51
User entered empty.	Donna Toepfer (b) (4)	05 Dec 2020 15:43:19

FDA-CBER-2022-1614-0698003

US3242269
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:13:41
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:02
User entered '0'	Donna Toepfer (b) (4)	05 Dec 2020 15:43:19

FDA-CBER-2022-1614-0698004

US3242269
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:13:41
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'Jul 2020'	(b) (4), (b) (6) System	05 Dec 2020 15:43:19

FDA-CBER-2022-1614-0698005

US3242269
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:13:41
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '2020'	(b) (4), (b) (6) System	05 Dec 2020 15:43:19

FDA-CBER-2022-1614-0698006

US3242269
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:13:41
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
User entered 'Jul 2020'	System	16 Dec 2020 19:20:32
User entered 'Jul 2029'	System	16 Dec 2020 19:02:51
User entered empty.	System	05 Dec 2020 15:43:19

FDA-CBER-2022-1614-0698007

US3242269
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:13:41
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
User entered '2020'	System	16 Dec 2020 19:20:32
User entered '2029'	System	16 Dec 2020 19:02:51
User entered empty.	System	05 Dec 2020 15:43:19

FDA-CBER-2022-1614-0698008

US3242269
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:13:41
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:02
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 03:56:01
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 03:56:01
Data point term sent to Coder	System	05 Dec 2020 15:44:25
User entered 'Asthma, episodic'	Donna Toepfer (b) (4)	05 Dec 2020 15:43:36

FDA-CBER-2022-1614-0698009

US3242269
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:13:41
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:02
User entered 'Un UNK 1985'	Donna Toepfer (b) (4)	05 Dec 2020 15:43:36

FDA-CBER-2022-1614-0698010

US3242269
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:02
User entered '0'	Donna Toepfer (b) (4)	05 Dec 2020 15:43:36

FDA-CBER-2022-1614-0698011

US3242269
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:13:41
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:02
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	05 Dec 2020 15:43:36

FDA-CBER-2022-1614-0698012

US3242269
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:13:41
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:02
User entered empty.	Donna Toepfer (b) (4)	05 Dec 2020 15:43:36

FDA-CBER-2022-1614-0698013

US3242269
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:13:41
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:02
User entered '0'	Donna Toepfer (b) (4)	05 Dec 2020 15:43:36

FDA-CBER-2022-1614-0698014

US3242269
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:13:41
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'Jan 1985'	(b) (4), (b) (6) System	05 Dec 2020 15:43:36

FDA-CBER-2022-1614-0698015

US3242269
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:13:41
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1985'	(b) (4), (b) (6) System	05 Dec 2020 15:43:36

FDA-CBER-2022-1614-0698016

US3242269
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:13:41
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	05 Dec 2020 15:43:36

FDA-CBER-2022-1614-0698017

US3242269
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:13:41
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	05 Dec 2020 15:43:36

FDA-CBER-2022-1614-0698018

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:27
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:26:34

FDA-CBER-2022-1614-0698019

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:30
User entered '1 Sep 2020'	Donna Toepfer (b) (4)	01 Sep 2020 16:26:34

FDA-CBER-2022-1614-0698020

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:32
User entered '11:28'	Donna Toepfer (b) (4)	01 Sep 2020 16:26:34

FDA-CBER-2022-1614-0698021

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1 Sep 2020 11:28'	(b) (4), (b) (6) System	01 Sep 2020 16:26:34

FDA-CBER-2022-1614-0698022

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:48
User entered '68' in	Donna Toepfer (b) (4)	01 Sep 2020 16:26:34
DataPoint set to visible.	System	01 Sep 2020 16:23:41

FDA-CBER-2022-1614-0698023

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:49
User entered '165' lb	Donna Toepfer (b) (4)	01 Sep 2020 16:26:34
DataPoint set to visible.	System	01 Sep 2020 16:23:41

FDA-CBER-2022-1614-0698024

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
User entered '25.14062'	System	01 Sep 2020 16:26:34
DataPoint set to visible.	System	01 Sep 2020 16:23:41

FDA-CBER-2022-1614-0698025

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	01 Sep 2020 16:26:34
DataPoint set to visible.	System	01 Sep 2020 16:23:41

FDA-CBER-2022-1614-0698026

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:54
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	01 Sep 2020 16:26:34

FDA-CBER-2022-1614-0698027

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:54
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:26:34

FDA-CBER-2022-1614-0698028

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:54
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:26:34

FDA-CBER-2022-1614-0698029

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:54
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	01 Sep 2020 16:26:34

FDA-CBER-2022-1614-0698030

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'bpm'	(b) (4), (b) (6) System	01 Sep 2020 16:26:34

FDA-CBER-2022-1614-0698031

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:54
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	01 Sep 2020 16:26:34

FDA-CBER-2022-1614-0698032

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'breaths/min'	(b) (4), (b) (6) System	01 Sep 2020 16:26:34

FDA-CBER-2022-1614-0698033

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:54
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	01 Sep 2020 16:26:34

FDA-CBER-2022-1614-0698034

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
User entered 'mmHg'	System	01 Sep 2020 16:26:34

FDA-CBER-2022-1614-0698035

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:00:54
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	01 Sep 2020 16:26:34

FDA-CBER-2022-1614-0698036

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'mmHg'	(b) (4), (b) (6) System	01 Sep 2020 16:26:34

FDA-CBER-2022-1614-0698037

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698038

US3242269
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698039

US3242269
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 16:13:41
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:01:07
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:26:41

FDA-CBER-2022-1614-0698040

US3242269
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 16:13:41
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:01:10
User entered '1 Sep 2020'	Donna Toepfer (b) (4)	01 Sep 2020 16:26:41

FDA-CBER-2022-1614-0698041

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:02:49
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

FDA-CBER-2022-1614-0698042

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:02:49
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

FDA-CBER-2022-1614-0698043

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41

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) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:02:49
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

FDA-CBER-2022-1614-0698044

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41
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) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:02:49
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

FDA-CBER-2022-1614-0698045

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:02:49
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

FDA-CBER-2022-1614-0698046

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41
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)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:02:49
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41
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)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:02:49
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41
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)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:02:49
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

FDA-CBER-2022-1614-0698049

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41
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) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:02:49
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

FDA-CBER-2022-1614-0698050

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41
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) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:02:49
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

FDA-CBER-2022-1614-0698051

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41
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) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:02:49
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

FDA-CBER-2022-1614-0698052

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:02:49
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

FDA-CBER-2022-1614-0698053

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:02:49
User entered 'retired, shops in the community several times a week'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

FDA-CBER-2022-1614-0698054

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

FDA-CBER-2022-1614-0698055

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:02:49
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

FDA-CBER-2022-1614-0698056

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41

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) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:02:49
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

FDA-CBER-2022-1614-0698057

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41
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) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:02:49
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41
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)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:02:49
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

FDA-CBER-2022-1614-0698059

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:02:49
User entered '1'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

FDA-CBER-2022-1614-0698060

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

FDA-CBER-2022-1614-0698061

US3242269
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:13:41
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:02:49
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:27:15

FDA-CBER-2022-1614-0698062

US3242269
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:13:41
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:03:23
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:44

US3242269
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:13:41
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:03:25
User entered '1 Sep 2020'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:44

FDA-CBER-2022-1614-0698064

US3242269
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:13:41
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:03:29
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:44

FDA-CBER-2022-1614-0698065

US3242269
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:13:41
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'VISIT1'	(b) (4), (b) (6) System	01 Sep 2020 16:27:44

FDA-CBER-2022-1614-0698066

US3242269
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:13:41
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:04:06
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 16:35:18

FDA-CBER-2022-1614-0698067

US3242269
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:13:41
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:04:06
User entered '189359'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 16:35:18

FDA-CBER-2022-1614-0698068

US3242269
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:13:41
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:04:06
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 16:35:18

FDA-CBER-2022-1614-0698069

US3242269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:13:41

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)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:04:06
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:53

US3242269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:13:41

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)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:04:06
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:53

US3242269
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:13:41
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:04:06
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:53

FDA-CBER-2022-1614-0698072

US3242269
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:13:41
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:04:06
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:53

FDA-CBER-2022-1614-0698073

US3242269
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:13:41
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:04:06
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:27:53

FDA-CBER-2022-1614-0698074

US3242269
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:13:41
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:14
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	23 Sep 2020 18:52:24
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:56:12
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:56:11

FDA-CBER-2022-1614-0698075

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:13:41
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698076

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:13:41
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:13:41
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698078

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:13:41
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698079

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698080

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698081

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered '1 Sep 2020'	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698082

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered '11:45'	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698083

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1 Sep 2020 11:45'	(b) (4), (b) (6) System	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698084

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered '98.4' F	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698085

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698086

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698087

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered '76'	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698088

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'bpm'	(b) (4), (b) (6) System	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698089

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered '18'	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698090

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'breaths/min'	(b) (4), (b) (6) System	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698091

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered '132'	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'mmHg'	(b) (4), (b) (6) System	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698093

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered '80'	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'mmHg'	(b) (4), (b) (6) System	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698095

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:13:41
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698096

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:13:41
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User accepted default value 'Post-Dose (POSTDOSE)'	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698098

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698099

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered '1 Sep 2020'	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698100

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered '13:14'	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698101

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1 Sep 2020 13:14'	(b) (4), (b) (6) System	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698102

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered '97.9' F	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698103

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698104

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698105

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered '72'	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698106

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'bpm'	(b) (4), (b) (6) System	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698107

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered '16'	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698108

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'breaths/min'	(b) (4), (b) (6) System	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698109

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered '134'	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698110

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'mmHg'	(b) (4), (b) (6) System	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698111

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:36
User entered '78'	Donna Toepfer (b) (4)	01 Sep 2020 17:51:41

US3242269
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'mmHg'	(b) (4), (b) (6) System	01 Sep 2020 17:51:41

FDA-CBER-2022-1614-0698113

US3242269
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 16:13:41
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:41
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:43:24

FDA-CBER-2022-1614-0698114

US3242269
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 16:13:41
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:05:43
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:43:24

FDA-CBER-2022-1614-0698115

US3242269
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:13:41
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:06:40
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698116

US3242269
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:13:41
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:06:50
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:47:08

US3242269
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:13:41

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)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:06:50
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698118

US3242269
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:13:41
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698119

US3242269
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:13:41
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:06:50
User entered '1 Sep 2020'	Donna Toepfer (b) (4)	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698120

US3242269
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:13:41
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:06:50
User entered '12:44'	Donna Toepfer (b) (4)	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698121

US3242269
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:13:41
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1 Sep 2020 12:44'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698122

US3242269
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:13:41
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:06:50
User entered 'Left Arm (LEFT ARM)'	Donna Toepfer (b) (4)	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698123

US3242269
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:13:41
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 20:06:50
User entered 'ONCE'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698124

US3242269
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:13:41
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698125

US3242269
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:13:41
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:07:01
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:47:19

FDA-CBER-2022-1614-0698126

US3242269
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:13:41
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:07:01
User entered '1 Sep 2020'	Donna Toepfer (b) (4)	01 Sep 2020 16:47:19

FDA-CBER-2022-1614-0698127

US3242269
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:13:41
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:07:01
User entered '12:30'	Donna Toepfer (b) (4)	01 Sep 2020 16:47:19

FDA-CBER-2022-1614-0698128

US3242269
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:13:41
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1 Sep 2020 12:30'	(b) (4), (b) (6) System	01 Sep 2020 16:47:19

FDA-CBER-2022-1614-0698129

US3242269
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 16:13:41
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:07:16
User entered '1 Sep 2020'	Donna Toepfer (b) (4)	01 Sep 2020 16:47:38

FDA-CBER-2022-1614-0698130

US3242269
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:13:41
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Donna Toepfer (b) (4)	01 Sep 2020 16:47:38

FDA-CBER-2022-1614-0698131

US3242269
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:13:41
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:07:16
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:47:38

FDA-CBER-2022-1614-0698132

US3242269
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:13:41
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:07:16
User entered '12:25'	Donna Toepfer (b) (4)	01 Sep 2020 16:47:38

FDA-CBER-2022-1614-0698133

US3242269
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:13:41
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1 Sep 2020 12:25'	(b) (4), (b) (6) System	01 Sep 2020 16:47:38

FDA-CBER-2022-1614-0698134

US3242269
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:13:41
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Donna Toepfer (b) (4)	01 Sep 2020 16:47:38

FDA-CBER-2022-1614-0698135

US3242269
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:13:41
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:07:16
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:47:38

FDA-CBER-2022-1614-0698136

US3242269
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:13:41
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:07:16
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:47:38

US3242269
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:13:41
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	01 Sep 2020 16:47:38

FDA-CBER-2022-1614-0698138

US3242269
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:12:08
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:43:42

FDA-CBER-2022-1614-0698139

US3242269
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	01 Sep 2020 16:43:42

FDA-CBER-2022-1614-0698140

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698141

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T13:22:28', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '7c229fa3-88fa-4b3e-bf7a-885e08a85978'	System	01 Sep 2020 17:23:12
User entered 'Yes (Y)'	System	01 Sep 2020 17:23:12

FDA-CBER-2022-1614-0698142

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T13:22:42', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '7c229fa3-88fa-4b3e-bf7a-885e08a85978'	System	01 Sep 2020 17:23:12
User entered '97.9'	System	01 Sep 2020 17:23:12

FDA-CBER-2022-1614-0698143

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T13:22:48', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '7c229fa3-88fa-4b3e-bf7a-885e08a85978'	System	01 Sep 2020 17:23:12
User entered 'No (N)'	System	01 Sep 2020 17:23:12

FDA-CBER-2022-1614-0698144

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T13:23:07', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '7c229fa3-88fa-4b3e-bf7a-885e08a85978'	System	01 Sep 2020 17:23:12
User entered '01 Sep 2020 13:23'	System	01 Sep 2020 17:23:12

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '01 Sep 2020 13:04'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698146

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '01 Sep 2020 15:34'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698147

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698148

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T18:27:11', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '49745da3-2750-4d0b-a35c-72ad160976f0'	System	01 Sep 2020 22:27:53
User entered 'Yes (Y)'	System	01 Sep 2020 22:27:53

FDA-CBER-2022-1614-0698149

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T18:27:22', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '49745da3-2750-4d0b-a35c-72ad160976f0'	(b) (4), (b) (6) System	01 Sep 2020 22:27:53
User entered '97.7'	System	01 Sep 2020 22:27:53

FDA-CBER-2022-1614-0698150

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T18:27:29', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '49745da3-2750-4d0b-a35c-72ad160976f0'	(b) (4), (b) (6) System	01 Sep 2020 22:27:53
User entered 'No (N)'	System	01 Sep 2020 22:27:53

FDA-CBER-2022-1614-0698151

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T18:27:51', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '49745da3-2750-4d0b-a35c-72ad160976f0'	System	01 Sep 2020 22:27:53
User entered '01 Sep 2020 18:27'	System	01 Sep 2020 22:27:53

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '01 Sep 2020 16:29'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698153

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '02 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698154

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 2'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698155

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:13:41
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-02T19:35:31', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '26711790-e000-4a29-9643-b07f4bfc5cf1'	System	02 Sep 2020 23:36:11
User entered 'Yes (Y)'	System	02 Sep 2020 23:36:11

FDA-CBER-2022-1614-0698156

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:13:41
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-02T19:35:44', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '26711790-e000-4a29-9643-b07f4bfc5cf1'	System	02 Sep 2020 23:36:11
User entered '98.0'	System	02 Sep 2020 23:36:11

FDA-CBER-2022-1614-0698157

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:13:41
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-02T19:35:51', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '26711790-e000-4a29-9643-b07f4bfc5cf1'	System	02 Sep 2020 23:36:11
User entered 'No (N)'	System	02 Sep 2020 23:36:11

FDA-CBER-2022-1614-0698158

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-02T19:36:05', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '26711790-e000-4a29-9643-b07f4bfc5cf1'	System	02 Sep 2020 23:36:11
User entered '02 Sep 2020 19:36'	System	02 Sep 2020 23:36:11

FDA-CBER-2022-1614-0698159

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '02 Sep 2020 12:00'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698160

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '03 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698161

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 3'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698162

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:13:41
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-03T19:10:30', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'bb9ccdf0-9f6a-4dd3-84ab-63aeedb96978'	System	03 Sep 2020 23:11:04
User entered 'Yes (Y)'	System	03 Sep 2020 23:11:04

FDA-CBER-2022-1614-0698163

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:13:41
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-03T19:10:38', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'bb9ccdf0-9f6a-4dd3-84ab-63aeedb96978'	System	03 Sep 2020 23:11:04
User entered '98.8'	System	03 Sep 2020 23:11:04

FDA-CBER-2022-1614-0698164

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:13:41
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-03T19:10:45', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'bb9ccdf0-9f6a-4dd3-84ab-63aeedb96978'	System	03 Sep 2020 23:11:04
User entered 'No (N)'	System	03 Sep 2020 23:11:04

FDA-CBER-2022-1614-0698165

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-03T19:10:59', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'bb9ccdf0-9f6a-4dd3-84ab-63aeedb96978'	System	03 Sep 2020 23:11:04
User entered '03 Sep 2020 19:10'	System	03 Sep 2020 23:11:04

FDA-CBER-2022-1614-0698166

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '03 Sep 2020 12:00'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698167

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '04 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698168

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 4'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698169

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:13:41
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-04T19:24:17', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'dec1ebcd-433a-4689-b157-04c2aadbb692'	System	04 Sep 2020 23:24:54
User entered 'Yes (Y)'	System	04 Sep 2020 23:24:54

FDA-CBER-2022-1614-0698170

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:13:41
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-04T19:24:28', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'dec1ebcd-433a-4689-b157-04c2aadbb692'	System	04 Sep 2020 23:24:54
User entered '98.6'	System	04 Sep 2020 23:24:54

FDA-CBER-2022-1614-0698171

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:13:41
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-04T19:24:36', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'dec1ebcd-433a-4689-b157-04c2aadbb692'	System	04 Sep 2020 23:24:54
User entered 'No (N)'	System	04 Sep 2020 23:24:54

FDA-CBER-2022-1614-0698172

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-04T19:24:51', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'dec1ebcd-433a-4689-b157-04c2aadbb692'	System	04 Sep 2020 23:24:54
User entered '04 Sep 2020 19:24'	System	04 Sep 2020 23:24:54

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '04 Sep 2020 12:00'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698174

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698175

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 5'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698176

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:13:41
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-05T19:08:24', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '91a46d53-53fb-45e3-9973-0aced3c9dadf'	(b) (4), (b) (6) System	05 Sep 2020 23:09:24
User entered 'Yes (Y)'	System	05 Sep 2020 23:09:24

FDA-CBER-2022-1614-0698177

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:13:41
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-05T19:08:50', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '91a46d53-53fb-45e3-9973-0aced3c9dadf'	System	05 Sep 2020 23:09:24
User entered '98.4'	System	05 Sep 2020 23:09:24

FDA-CBER-2022-1614-0698178

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:13:41
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-05T19:08:57', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '91a46d53-53fb-45e3-9973-0aced3c9dadf'	(b) (4), (b) (6) System	05 Sep 2020 23:09:24
User entered 'No (N)'	System	05 Sep 2020 23:09:24

FDA-CBER-2022-1614-0698179

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-05T19:09:21', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '91a46d53-53fb-45e3-9973-0aced3c9dadf'	System	05 Sep 2020 23:09:24
User entered '05 Sep 2020 19:09'	System	05 Sep 2020 23:09:24

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698181

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698182

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 6'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698183

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:13:41
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-06T20:44:20', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '863035bb-c481-43ab-ab11-fb89ab829751'	(b) (4), (b) (6) System	07 Sep 2020 00:45:04
User entered 'Yes (Y)'	System	07 Sep 2020 00:45:04

FDA-CBER-2022-1614-0698184

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:13:41
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-06T20:44:44', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '863035bb-c481-43ab-ab11-fb89ab829751'	System	07 Sep 2020 00:45:04
User entered '98.5'	System	07 Sep 2020 00:45:04

FDA-CBER-2022-1614-0698185

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:13:41
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-06T20:44:49', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '863035bb-c481-43ab-ab11-fb89ab829751'	System	07 Sep 2020 00:45:04
User entered 'No (N)'	System	07 Sep 2020 00:45:04

FDA-CBER-2022-1614-0698186

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-06T20:45:00', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '863035bb-c481-43ab-ab11-fb89ab829751'	System	07 Sep 2020 00:45:04
User entered '06 Sep 2020 20:45'	System	07 Sep 2020 00:45:04

FDA-CBER-2022-1614-0698187

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698188

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698189

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 7'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698190

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:13:41
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698191

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:13:41
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698192

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:13:41
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698193

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:13:41
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698194

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:13:41
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698195

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698196

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '07 Sep 2020 12:00'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698197

US3242269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '08 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698198

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698199

US3242269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:41

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T13:23:49', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '8e278dd1-6fd6-48ad-9b61-a83b4f96f338'	System	01 Sep 2020 17:24:31
User entered 'None (1)'	System	01 Sep 2020 17:24:31

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T13:23:56', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '8e278dd1-6fd6-48ad-9b61-a83b4f96f338'	System	01 Sep 2020 17:24:31
User entered 'No (N)'	System	01 Sep 2020 17:24:31

FDA-CBER-2022-1614-0698201

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T13:24:03', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '8e278dd1-6fd6-48ad-9b61-a83b4f96f338'	System	01 Sep 2020 17:24:31
User entered 'No (N)'	System	01 Sep 2020 17:24:31

US3242269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T13:24:17', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '8e278dd1-6fd6-48ad-9b61-a83b4f96f338'	System	01 Sep 2020 17:24:31
User entered 'None (1)'	System	01 Sep 2020 17:24:31

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T13:24:29', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '8e278dd1-6fd6-48ad-9b61-a83b4f96f338'	System	01 Sep 2020 17:24:31
User entered '01 Sep 2020 13:24'	System	01 Sep 2020 17:24:31

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '01 Sep 2020 13:04'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698205

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '01 Sep 2020 15:34'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698206

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698207

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T18:28:22', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '8c53956b-a33a-4929-abfc-234187f63858'	System	01 Sep 2020 22:29:15
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 22:29:15

FDA-CBER-2022-1614-0698208

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T18:28:28', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '8c53956b-a33a-4929-abfc-234187f63858'	(b) (4), (b) (6) System	01 Sep 2020 22:29:15
User entered 'No (N)'	System	01 Sep 2020 22:29:15

FDA-CBER-2022-1614-0698209

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T18:28:37', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '8c53956b-a33a-4929-abfc-234187f63858'	(b) (4), (b) (6) System	01 Sep 2020 22:29:15
User entered 'No (N)'	System	01 Sep 2020 22:29:15

FDA-CBER-2022-1614-0698210

US3242269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:13:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T18:28:58', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '8c53956b-a33a-4929-abfc-234187f63858'	System	01 Sep 2020 22:29:15
User entered 'None (1)'	System	01 Sep 2020 22:29:15

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T18:29:14', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '8c53956b-a33a-4929-abfc-234187f63858'	System	01 Sep 2020 22:29:15
User entered '01 Sep 2020 18:29'	System	01 Sep 2020 22:29:15

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '01 Sep 2020 16:29'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698213

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '02 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698214

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 2'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698215

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:13:41
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-02T19:36:37', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'beb7611b-657a-451c-a423-2eb5b25914bb'	System	02 Sep 2020 23:37:34
User entered 'None (1)'	System	02 Sep 2020 23:37:34

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:13:41
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-02T19:36:47', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'beb7611b-657a-451c-a423-2eb5b25914bb'	(b) (4), (b) (6) System	02 Sep 2020 23:37:34
User entered 'No (N)'	System	02 Sep 2020 23:37:34

FDA-CBER-2022-1614-0698217

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:13:41
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-02T19:36:53', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'beb7611b-657a-451c-a423-2eb5b25914bb'	(b) (4), (b) (6) System	02 Sep 2020 23:37:34
User entered 'No (N)'	System	02 Sep 2020 23:37:34

FDA-CBER-2022-1614-0698218

US3242269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:13:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-02T19:37:19', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'beb7611b-657a-451c-a423-2eb5b25914bb'	System	02 Sep 2020 23:37:34
User entered 'None (1)'	System	02 Sep 2020 23:37:34

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-02T19:37:32', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'beb7611b-657a-451c-a423-2eb5b25914bb'	System	02 Sep 2020 23:37:34
User entered '02 Sep 2020 19:37'	System	02 Sep 2020 23:37:34

FDA-CBER-2022-1614-0698220

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '02 Sep 2020 12:00'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698221

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '03 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698222

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 3'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698223

US3242269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:41

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-03T19:11:21', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '581c0ddb-2872-4dd1-894c-99cfb0fb1a54'	System	03 Sep 2020 23:12:01
User entered 'None (1)'	System	03 Sep 2020 23:12:01

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:13:41
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-03T19:11:27', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '581c0ddb-2872-4dd1-894c-99cfb0fb1a54'	(b) (4), (b) (6) System	03 Sep 2020 23:12:01
User entered 'No (N)'	System	03 Sep 2020 23:12:01

FDA-CBER-2022-1614-0698225

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:13:41
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-03T19:11:33', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '581c0ddb-2872-4dd1-894c-99cfb0fb1a54'	System	03 Sep 2020 23:12:01
User entered 'No (N)'	System	03 Sep 2020 23:12:01

FDA-CBER-2022-1614-0698226

US3242269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-03T19:11:45', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '581c0ddb-2872-4dd1-894c-99cfb0fb1a54'	(b) (4), (b) (6) System	03 Sep 2020 23:12:01
User entered 'None (1)'	System	03 Sep 2020 23:12:01

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-03T19:11:59', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '581c0ddb-2872-4dd1-894c-99cfb0fb1a54'	System	03 Sep 2020 23:12:01
User entered '03 Sep 2020 19:11'	System	03 Sep 2020 23:12:01

FDA-CBER-2022-1614-0698228

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '03 Sep 2020 12:00'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698229

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '04 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698230

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 4'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698231

US3242269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:13:41

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-04T19:25:04', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'bd284a1f-0502-43b6-baa5-a428aaafdfc2'	System	04 Sep 2020 23:25:55
User entered 'None (1)'	System	04 Sep 2020 23:25:55

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:13:41
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-04T19:25:10', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'bd284a1f-0502-43b6-baa5-a428aaafdfc2'	System	04 Sep 2020 23:25:55
User entered 'No (N)'	System	04 Sep 2020 23:25:55

FDA-CBER-2022-1614-0698233

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:13:41
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-04T19:25:17', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'bd284a1f-0502-43b6-baa5-a428aaafdfc2'	System	04 Sep 2020 23:25:55
User entered 'No (N)'	System	04 Sep 2020 23:25:55

FDA-CBER-2022-1614-0698234

US3242269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:13:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-04T19:25:36', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'bd284a1f-0502-43b6-baa5-a428aaafdfc2'	System	04 Sep 2020 23:25:55
User entered 'None (1)'	System	04 Sep 2020 23:25:55

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-04T19:25:51', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'bd284a1f-0502-43b6-baa5-a428aaafdfc2'	System	04 Sep 2020 23:25:55
User entered '04 Sep 2020 19:25'	System	04 Sep 2020 23:25:55

FDA-CBER-2022-1614-0698236

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '04 Sep 2020 12:00'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698237

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698238

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 5'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698239

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:13:41
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-05T19:09:55', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd938ce06-7a93-4443-ab7e-cb747f4803a0'	System	05 Sep 2020 23:10:41
User entered 'None (1)'	System	05 Sep 2020 23:10:41

FDA-CBER-2022-1614-0698240

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:13:41
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-05T19:10:01', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd938ce06-7a93-4443-ab7e-cb747f4803a0'	(b) (4), (b) (6) System	05 Sep 2020 23:10:41
User entered 'No (N)'	System	05 Sep 2020 23:10:41

FDA-CBER-2022-1614-0698241

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:13:41
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-05T19:10:07', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd938ce06-7a93-4443-ab7e-cb747f4803a0'	System	05 Sep 2020 23:10:41
User entered 'No (N)'	System	05 Sep 2020 23:10:41

FDA-CBER-2022-1614-0698242

US3242269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:13:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-05T19:10:24', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd938ce06-7a93-4443-ab7e-cb747f4803a0'	(b) (4), (b) (6) System	05 Sep 2020 23:10:41
User entered 'None (1)'	System	05 Sep 2020 23:10:41

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-05T19:10:39', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd938ce06-7a93-4443-ab7e-cb747f4803a0'	System	05 Sep 2020 23:10:41
User entered '05 Sep 2020 19:10'	System	05 Sep 2020 23:10:41

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698245

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698246

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 6'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698247

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:13:41
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-06T20:45:15', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '8dc4ed97-4a84-409d-a09b-1e03aa514063'	(b) (4), (b) (6) System	07 Sep 2020 00:45:49
User entered 'None (1)'	System	07 Sep 2020 00:45:49

FDA-CBER-2022-1614-0698248

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:13:41
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-06T20:45:20', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '8dc4ed97-4a84-409d-a09b-1e03aa514063'	System	07 Sep 2020 00:45:49
User entered 'No (N)'	System	07 Sep 2020 00:45:49

FDA-CBER-2022-1614-0698249

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:13:41
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-06T20:45:26', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '8dc4ed97-4a84-409d-a09b-1e03aa514063'	(b) (4), (b) (6) System	07 Sep 2020 00:45:49
User entered 'No (N)'	System	07 Sep 2020 00:45:49

FDA-CBER-2022-1614-0698250

US3242269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:13:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-06T20:45:36', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '8dc4ed97-4a84-409d-a09b-1e03aa514063'	(b) (4), (b) (6) System	07 Sep 2020 00:45:49
User entered 'None (1)'	System	07 Sep 2020 00:45:49

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-06T20:45:47', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '8dc4ed97-4a84-409d-a09b-1e03aa514063'	System	07 Sep 2020 00:45:49
User entered '06 Sep 2020 20:45'	System	07 Sep 2020 00:45:49

FDA-CBER-2022-1614-0698252

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698253

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698254

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 7'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698255

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:13:41
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698256

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:13:41
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698257

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:13:41
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698258

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:13:41
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698259

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:13:41
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698260

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:13:41
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698261

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698262

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '07 Sep 2020 12:00'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698263

US3242269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '08 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698264

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698265

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T13:24:41', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '5e14f9e4-c0c4-4eb2-9869-38a01c3c491c'	System	01 Sep 2020 17:25:44
User entered 'None (0)'	System	01 Sep 2020 17:25:44

FDA-CBER-2022-1614-0698266

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T13:24:55', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '5e14f9e4-c0c4-4eb2-9869-38a01c3c491c'	System	01 Sep 2020 17:25:44
User entered 'None (0)'	System	01 Sep 2020 17:25:44

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T13:25:11', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '5e14f9e4-c0c4-4eb2-9869-38a01c3c491c'	System	01 Sep 2020 17:25:44
User entered 'None (0)'	System	01 Sep 2020 17:25:44

FDA-CBER-2022-1614-0698268

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T13:25:15', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '5e14f9e4-c0c4-4eb2-9869-38a01c3c491c'	System	01 Sep 2020 17:25:44
User entered 'None (0)'	System	01 Sep 2020 17:25:44

FDA-CBER-2022-1614-0698269

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T13:25:20', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '5e14f9e4-c0c4-4eb2-9869-38a01c3c491c'	System	01 Sep 2020 17:25:44
User entered 'None (0)'	System	01 Sep 2020 17:25:44

FDA-CBER-2022-1614-0698270

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T13:25:24', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '5e14f9e4-c0c4-4eb2-9869-38a01c3c491c'	System	01 Sep 2020 17:25:44
User entered 'None (0)'	System	01 Sep 2020 17:25:44

FDA-CBER-2022-1614-0698271

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
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) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T13:25:35', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '5e14f9e4-c0c4-4eb2-9869-38a01c3c491c'	System	01 Sep 2020 17:25:44
User entered 'No (N)'	System	01 Sep 2020 17:25:44

FDA-CBER-2022-1614-0698272

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T13:25:42', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '5e14f9e4-c0c4-4eb2-9869-38a01c3c491c'	System	01 Sep 2020 17:25:44
User entered '01 Sep 2020 13:25'	System	01 Sep 2020 17:25:44

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '01 Sep 2020 13:04'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698274

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '01 Sep 2020 15:34'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698275

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698276

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T18:29:27', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'c62ccd31-6d81-42d8-a2e2-d7ec8873b9f0'	(b) (4), (b) (6) System	01 Sep 2020 22:31:10
User entered 'None (0)'	System	01 Sep 2020 22:31:10

FDA-CBER-2022-1614-0698277

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T18:29:38', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'c62ccd31-6d81-42d8-a2e2-d7ec8873b9f0'	(b) (4), (b) (6) System	01 Sep 2020 22:31:10
User entered 'None (0)'	System	01 Sep 2020 22:31:10

FDA-CBER-2022-1614-0698278

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T18:29:57', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'c62ccd31-6d81-42d8-a2e2-d7ec8873b9f0'	System	01 Sep 2020 22:31:10
User entered 'None (0)'	System	01 Sep 2020 22:31:10

FDA-CBER-2022-1614-0698279

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T18:30:09', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'c62ccd31-6d81-42d8-a2e2-d7ec8873b9f0'	System	01 Sep 2020 22:31:10
User entered 'None (0)'	System	01 Sep 2020 22:31:10

FDA-CBER-2022-1614-0698280

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T18:30:20', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'c62ccd31-6d81-42d8-a2e2-d7ec8873b9f0'	(b) (4), (b) (6) System	01 Sep 2020 22:31:10
User entered 'None (0)'	System	01 Sep 2020 22:31:10

FDA-CBER-2022-1614-0698281

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T18:30:27', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'c62ccd31-6d81-42d8-a2e2-d7ec8873b9f0'	System	01 Sep 2020 22:31:10
User entered 'None (0)'	System	01 Sep 2020 22:31:10

FDA-CBER-2022-1614-0698282

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
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) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T18:30:47', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'c62ccd31-6d81-42d8-a2e2-d7ec8873b9f0'	System	01 Sep 2020 22:31:10
User entered 'No (N)'	System	01 Sep 2020 22:31:10

FDA-CBER-2022-1614-0698283

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-01T18:31:04', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'c62ccd31-6d81-42d8-a2e2-d7ec8873b9f0'	System	01 Sep 2020 22:31:10
User entered '01 Sep 2020 18:31'	System	01 Sep 2020 22:31:10

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '01 Sep 2020 16:29'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698285

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '02 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698286

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 2'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698287

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-02T19:37:49', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '1666a57a-a556-481e-bf98-07bf351d5a67'	System	02 Sep 2020 23:39:18
User entered 'None (0)'	System	02 Sep 2020 23:39:18

FDA-CBER-2022-1614-0698288

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-02T19:38:00', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '1666a57a-a556-481e-bf98-07bf351d5a67'	System	02 Sep 2020 23:39:18
User entered 'None (0)'	System	02 Sep 2020 23:39:18

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-02T19:38:08', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '1666a57a-a556-481e-bf98-07bf351d5a67'	System	02 Sep 2020 23:39:18
User entered 'None (0)'	System	02 Sep 2020 23:39:18

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-02T19:38:18', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '1666a57a-a556-481e-bf98-07bf351d5a67'	System	02 Sep 2020 23:39:18
User entered 'None (0)'	System	02 Sep 2020 23:39:18

FDA-CBER-2022-1614-0698291

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-02T19:38:28', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '1666a57a-a556-481e-bf98-07bf351d5a67'	System	02 Sep 2020 23:39:18
User entered 'None (0)'	System	02 Sep 2020 23:39:18

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-02T19:38:33', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '1666a57a-a556-481e-bf98-07bf351d5a67'	System	02 Sep 2020 23:39:18
User entered 'None (0)'	System	02 Sep 2020 23:39:18

FDA-CBER-2022-1614-0698293

US3242269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:13:41

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)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-02T19:38:51', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '1666a57a-a556-481e-bf98-07bf351d5a67'	(b) (4), (b) (6) System	02 Sep 2020 23:39:18
User entered 'No (N)'	System	02 Sep 2020 23:39:18

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-02T19:39:15', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '1666a57a-a556-481e-bf98-07bf351d5a67'	System	02 Sep 2020 23:39:18
User entered '02 Sep 2020 19:39'	System	02 Sep 2020 23:39:18

FDA-CBER-2022-1614-0698295

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '02 Sep 2020 12:00'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698296

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '03 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698297

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 3'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698298

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-03T19:12:28', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'c7c6fe94-1d88-4e30-8a9a-389cfc86e084'	System	03 Sep 2020 23:13:33
User entered 'None (0)'	System	03 Sep 2020 23:13:33

FDA-CBER-2022-1614-0698299

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-03T19:12:35', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'c7c6fe94-1d88-4e30-8a9a-389cfc86e084'	System	03 Sep 2020 23:13:33
User entered 'None (0)'	System	03 Sep 2020 23:13:33

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-03T19:12:48', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'c7c6fe94-1d88-4e30-8a9a-389cfc86e084'	System	03 Sep 2020 23:13:33
User entered 'None (0)'	System	03 Sep 2020 23:13:33

FDA-CBER-2022-1614-0698301

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-03T19:12:53', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'c7c6fe94-1d88-4e30-8a9a-389cfc86e084'	System	03 Sep 2020 23:13:33
User entered 'None (0)'	System	03 Sep 2020 23:13:33

FDA-CBER-2022-1614-0698302

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-03T19:12:58', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'c7c6fe94-1d88-4e30-8a9a-389cfc86e084'	System	03 Sep 2020 23:13:33
User entered 'None (0)'	System	03 Sep 2020 23:13:33

FDA-CBER-2022-1614-0698303

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-03T19:13:03', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'c7c6fe94-1d88-4e30-8a9a-389cfc86e084'	System	03 Sep 2020 23:13:33
User entered 'None (0)'	System	03 Sep 2020 23:13:33

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
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)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-03T19:13:13', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'c7c6fe94-1d88-4e30-8a9a-389cfc86e084'	(b) (4), (b) (6) System	03 Sep 2020 23:13:33
User entered 'No (N)'	System	03 Sep 2020 23:13:33

FDA-CBER-2022-1614-0698305

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-03T19:13:30', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'c7c6fe94-1d88-4e30-8a9a-389cfc86e084'	System	03 Sep 2020 23:13:33
User entered '03 Sep 2020 19:13'	System	03 Sep 2020 23:13:33

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '03 Sep 2020 12:00'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698307

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '04 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698308

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 4'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698309

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-04T19:26:06', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'f672a950-712e-436e-bb13-3c0d790cffa0'	System	04 Sep 2020 23:27:10
User entered 'None (0)'	System	04 Sep 2020 23:27:10

FDA-CBER-2022-1614-0698310

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-04T19:26:13', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'f672a950-712e-436e-bb13-3c0d790cffa0'	(b) (4), (b) (6) System	04 Sep 2020 23:27:10
User entered 'None (0)'	System	04 Sep 2020 23:27:10

FDA-CBER-2022-1614-0698311

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-04T19:26:18', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'f672a950-712e-436e-bb13-3c0d790cffa0'	System	04 Sep 2020 23:27:10
User entered 'None (0)'	System	04 Sep 2020 23:27:10

FDA-CBER-2022-1614-0698312

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-04T19:26:24', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'f672a950-712e-436e-bb13-3c0d790cffa0'	System	04 Sep 2020 23:27:10
User entered 'None (0)'	System	04 Sep 2020 23:27:10

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-04T19:26:28', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'f672a950-712e-436e-bb13-3c0d790cffa0'	(b) (4), (b) (6) System	04 Sep 2020 23:27:10
User entered 'None (0)'	System	04 Sep 2020 23:27:10

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-04T19:26:33', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'f672a950-712e-436e-bb13-3c0d790cffa0'	System	04 Sep 2020 23:27:10
User entered 'None (0)'	System	04 Sep 2020 23:27:10

FDA-CBER-2022-1614-0698315

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
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)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-04T19:26:42', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'f672a950-712e-436e-bb13-3c0d790cffa0'	(b) (4), (b) (6) System	04 Sep 2020 23:27:10
User entered 'No (N)'	System	04 Sep 2020 23:27:10

FDA-CBER-2022-1614-0698316

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-04T19:27:09', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'f672a950-712e-436e-bb13-3c0d790cffa0'	System	04 Sep 2020 23:27:10
User entered '04 Sep 2020 19:27'	System	04 Sep 2020 23:27:10

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '04 Sep 2020 12:00'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698318

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698319

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 5'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698320

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-05T19:10:57', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '0d115710-f918-4256-adda-2dc3a574ac9c'	(b) (4), (b) (6) System	05 Sep 2020 23:12:39
User entered 'None (0)'	System	05 Sep 2020 23:12:39

FDA-CBER-2022-1614-0698321

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-05T19:11:05', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '0d115710-f918-4256-adda-2dc3a574ac9c'	System	05 Sep 2020 23:12:39
User entered 'None (0)'	System	05 Sep 2020 23:12:39

FDA-CBER-2022-1614-0698322

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-05T19:11:11', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '0d115710-f918-4256-adda-2dc3a574ac9c'	System	05 Sep 2020 23:12:39
User entered 'None (0)'	System	05 Sep 2020 23:12:39

FDA-CBER-2022-1614-0698323

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-05T19:11:20', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '0d115710-f918-4256-adda-2dc3a574ac9c'	System	05 Sep 2020 23:12:39
User entered 'None (0)'	System	05 Sep 2020 23:12:39

FDA-CBER-2022-1614-0698324

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-05T19:11:33', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '0d115710-f918-4256-adda-2dc3a574ac9c'	(b) (4), (b) (6) System	05 Sep 2020 23:12:39
User entered 'None (0)'	System	05 Sep 2020 23:12:39

FDA-CBER-2022-1614-0698325

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-05T19:11:44', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '0d115710-f918-4256-adda-2dc3a574ac9c'	System	05 Sep 2020 23:12:39
User entered 'None (0)'	System	05 Sep 2020 23:12:39

FDA-CBER-2022-1614-0698326

US3242269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:13:41

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)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-05T19:12:00', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '0d115710-f918-4256-adda-2dc3a574ac9c'	(b) (4), (b) (6) System	05 Sep 2020 23:12:39
User entered 'No (N)'	System	05 Sep 2020 23:12:39

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-05T19:12:37', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '0d115710-f918-4256-adda-2dc3a574ac9c'	System	05 Sep 2020 23:12:39
User entered '05 Sep 2020 19:12'	System	05 Sep 2020 23:12:39

FDA-CBER-2022-1614-0698328

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698329

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698330

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 6'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698331

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-06T20:45:57', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '681fa95f-cb12-4649-b45c-6585475c02c4'	System	07 Sep 2020 00:46:47
User entered 'None (0)'	System	07 Sep 2020 00:46:47

FDA-CBER-2022-1614-0698332

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-06T20:46:02', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '681fa95f-cb12-4649-b45c-6585475c02c4'	System	07 Sep 2020 00:46:47
User entered 'None (0)'	System	07 Sep 2020 00:46:47

FDA-CBER-2022-1614-0698333

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-06T20:46:07', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '681fa95f-cb12-4649-b45c-6585475c02c4'	System	07 Sep 2020 00:46:47
User entered 'None (0)'	System	07 Sep 2020 00:46:47

FDA-CBER-2022-1614-0698334

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-06T20:46:14', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '681fa95f-cb12-4649-b45c-6585475c02c4'	System	07 Sep 2020 00:46:47
User entered 'None (0)'	System	07 Sep 2020 00:46:47

FDA-CBER-2022-1614-0698335

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-06T20:46:18', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '681fa95f-cb12-4649-b45c-6585475c02c4'	System	07 Sep 2020 00:46:47
User entered 'None (0)'	System	07 Sep 2020 00:46:47

FDA-CBER-2022-1614-0698336

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-06T20:46:22', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '681fa95f-cb12-4649-b45c-6585475c02c4'	System	07 Sep 2020 00:46:47
User entered 'None (0)'	System	07 Sep 2020 00:46:47

FDA-CBER-2022-1614-0698337

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
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)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-06T20:46:31', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '681fa95f-cb12-4649-b45c-6585475c02c4'	(b) (4), (b) (6) System	07 Sep 2020 00:46:47
User entered 'No (N)'	System	07 Sep 2020 00:46:47

FDA-CBER-2022-1614-0698338

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-06T20:46:44', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '681fa95f-cb12-4649-b45c-6585475c02c4'	System	07 Sep 2020 00:46:47
User entered '06 Sep 2020 20:46'	System	07 Sep 2020 00:46:47

FDA-CBER-2022-1614-0698339

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698340

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698341

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 7'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698342

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698343

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698344

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698345

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698346

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698347

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698348

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
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) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698349

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30

FDA-CBER-2022-1614-0698350

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '07 Sep 2020 12:00'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698351

US3242269
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '08 Sep 2020 11:59'	(b) (4), (b) (6) System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698352

US3242269
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:14
User entered 'Yes (Y)'	Grace Newville (b) (4) (b) (4)	08 Sep 2020 16:52:32

US3242269
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:14
User entered '8 Sep 2020'	Grace Newville (b) (4) (b) (4)	08 Sep 2020 16:52:32

FDA-CBER-2022-1614-0698354

US3242269
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:14
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4) (b) (4)	08 Sep 2020 16:52:32

US3242269
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:14
User entered empty.	Grace Newville (b) (4) (b) (4)	08 Sep 2020 16:52:32

FDA-CBER-2022-1614-0698356

US3242269
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:14
User entered 'Yes (Y)'	Grace Newville (b) (4) (b) (4)	08 Sep 2020 16:52:35

FDA-CBER-2022-1614-0698357

US3242269
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	08 Sep 2020 16:52:35

FDA-CBER-2022-1614-0698358

US3242269
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Yes (Y)'	Grace Newville (b) (4) (b) (4)	17 Sep 2020 22:36:50

FDA-CBER-2022-1614-0698359

US3242269
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '17 Sep 2020'	Grace Newville (b) (4) (b) (4)	17 Sep 2020 22:36:50

FDA-CBER-2022-1614-0698360

US3242269
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4) (b) (4)	17 Sep 2020 22:36:50

FDA-CBER-2022-1614-0698361

US3242269
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Grace Newville (b) (4) (b) (4)	17 Sep 2020 22:36:50

FDA-CBER-2022-1614-0698362

US3242269
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Yes (Y)'	Grace Newville (b) (4) (b) (4)	17 Sep 2020 22:36:53

FDA-CBER-2022-1614-0698363

US3242269
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	17 Sep 2020 22:36:53

FDA-CBER-2022-1614-0698364

US3242269
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 15:56:30

US3242269
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '23 Sep 2020'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 15:56:30

FDA-CBER-2022-1614-0698366

US3242269
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 15:56:30

US3242269
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 15:56:30

FDA-CBER-2022-1614-0698368

US3242269
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 15:56:32

FDA-CBER-2022-1614-0698369

US3242269
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	30 Sep 2020 15:56:32

FDA-CBER-2022-1614-0698370

US3242269
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:13:41
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:33
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:50:05
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	13 Nov 2020 13:38:58
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 07:07:39
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 15:56:43

FDA-CBER-2022-1614-0698371

US3242269
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:13:41
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:33
User entered '30 Sep 2020'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 15:56:43

FDA-CBER-2022-1614-0698372

US3242269
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:13:41
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:33
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 15:56:43

FDA-CBER-2022-1614-0698373

US3242269
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:13:41
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'VISIT2'	(b) (4), (b) (6) System	30 Sep 2020 15:56:43

FDA-CBER-2022-1614-0698374

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User accepted default value 'Pre-Dose (PREDOSE)'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698375

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:37
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698376

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:37
User entered '30 Sep 2020'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698377

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:37
User entered '11:03'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698378

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '30 Sep 2020 11:03'	(b) (4), (b) (6) System	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698379

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:37
User entered '97.6' F	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698380

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:37
User entered 'Oral (Oral)'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698381

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:37
User entered empty.	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698382

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:37
User entered '92'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698383

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'bpm'	(b) (4), (b) (6) System	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698384

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:37
User entered '16'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698385

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'breaths/min'	(b) (4), (b) (6) System	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698386

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:37
User entered '122'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698387

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'mmHg'	(b) (4), (b) (6) System	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698388

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:37
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)	16 Oct 2020 15:15:01
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 'value is correct, ncs' (Site from System).	Donna Toepfer (b) (4)	30 Sep 2020 21:35:16
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	30 Sep 2020 20:08:00
User entered '50'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698389

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:13:41
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
User entered 'mmHg'	System	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698390

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User accepted default value 'Post-Dose (POSTDOSE)'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698391

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:37
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698392

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:37
User entered '30 Sep 2020'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698393

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:37
User entered '12:50'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698394

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '30 Sep 2020 12:50'	(b) (4), (b) (6) System	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698395

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:37
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	30 Sep 2020 20:08:19
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	30 Sep 2020 20:08:19
User entered '97.3' F reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:19
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	30 Sep 2020 20:08:00
User entered '97.3' C	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698396

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:37
User entered 'Oral (Oral)'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698397

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:37
User entered empty.	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698398

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:37
User entered '88' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	16 Dec 2020 19:07:18
User entered '62'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698399

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'bpm'	(b) (4), (b) (6) System	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698400

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:37
User entered '16'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698401

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'breaths/min'	(b) (4), (b) (6) System	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698402

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:37
User entered '126'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698403

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'mmHg'	(b) (4), (b) (6) System	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698404

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:37
User entered '62'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698405

US3242269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:13:41
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
User entered 'mmHg'	System	30 Sep 2020 20:08:00

FDA-CBER-2022-1614-0698406

US3242269
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:13:41
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:41
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 15:58:25

FDA-CBER-2022-1614-0698407

US3242269
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:13:41
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:41
User entered empty.	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 15:58:25

FDA-CBER-2022-1614-0698408

US3242269
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:13:41
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698409

US3242269
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:13:41
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:45
User entered empty.	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698410

US3242269
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:13:41

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) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:45
User entered empty.	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698411

US3242269
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:13:41
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698412

US3242269
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:13:41
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:45
User entered '30 Sep 2020'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698413

US3242269
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:13:41
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:45
User entered '12:15'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698414

US3242269
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:13:41
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '30 Sep 2020 12:15'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698415

US3242269
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:13:41
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:45
User entered 'Left Arm (LEFT ARM)'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698416

US3242269
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:13:41
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:45
User entered 'ONCE'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698417

US3242269
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:13:41
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698418

US3242269
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:13:41
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:49
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 16:00:16

FDA-CBER-2022-1614-0698419

US3242269
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:13:41
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:49
User entered '30 Sep 2020'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 16:00:16

FDA-CBER-2022-1614-0698420

US3242269
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:13:41
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:49
User entered '11:53'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 16:00:16

FDA-CBER-2022-1614-0698421

US3242269
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:13:41
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '30 Sep 2020 11:53'	(b) (4), (b) (6) System	30 Sep 2020 16:00:16

FDA-CBER-2022-1614-0698422

US3242269
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 16:13:41
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:53
User entered '30 Sep 2020'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 16:00:26

FDA-CBER-2022-1614-0698423

US3242269
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:13:41
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 16:00:26

FDA-CBER-2022-1614-0698424

US3242269
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:13:41
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:53
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 16:00:26

US3242269
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:13:41
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:53
User entered '11:45'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 16:00:26

FDA-CBER-2022-1614-0698426

US3242269
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:13:41
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '30 Sep 2020 11:45'	(b) (4), (b) (6) System	30 Sep 2020 16:00:26

FDA-CBER-2022-1614-0698427

US3242269
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:13:41
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 16:00:26

FDA-CBER-2022-1614-0698428

US3242269
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:13:41
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:53
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 16:00:26

FDA-CBER-2022-1614-0698429

US3242269
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:13:41
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:53
User entered empty.	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 16:00:26

FDA-CBER-2022-1614-0698430

US3242269
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:13:41
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	30 Sep 2020 16:00:26

FDA-CBER-2022-1614-0698431

US3242269
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:06:57
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	30 Sep 2020 16:00:47

FDA-CBER-2022-1614-0698432

US3242269
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	30 Sep 2020 16:00:47

FDA-CBER-2022-1614-0698433

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698434

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T12:47:38', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '8fd58d47-2db6-4058-8193-b96c40b644f8'	System	30 Sep 2020 16:48:26
User entered 'Yes (Y)'	System	30 Sep 2020 16:48:26

FDA-CBER-2022-1614-0698435

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T12:48:04', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '8fd58d47-2db6-4058-8193-b96c40b644f8'	System	30 Sep 2020 16:48:26
User entered '97.8'	System	30 Sep 2020 16:48:26

FDA-CBER-2022-1614-0698436

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T12:48:10', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '8fd58d47-2db6-4058-8193-b96c40b644f8'	(b) (4), (b) (6) System	30 Sep 2020 16:48:26
User entered 'No (N)'	System	30 Sep 2020 16:48:26

FDA-CBER-2022-1614-0698437

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T12:48:22', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '8fd58d47-2db6-4058-8193-b96c40b644f8'	System	30 Sep 2020 16:48:26
User entered '30 Sep 2020 12:48'	System	30 Sep 2020 16:48:26

FDA-CBER-2022-1614-0698438

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '30 Sep 2020 12:35'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698439

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '30 Sep 2020 15:05'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698440

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698441

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T16:05:04', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '6e34ad9e-1d4f-4c6d-ad3e-603fc72ece1a'	System	30 Sep 2020 20:05:45
User entered 'Yes (Y)'	System	30 Sep 2020 20:05:45

FDA-CBER-2022-1614-0698442

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T16:05:26', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '6e34ad9e-1d4f-4c6d-ad3e-603fc72ece1a'	System	30 Sep 2020 20:05:45
User entered '98.9'	System	30 Sep 2020 20:05:45

FDA-CBER-2022-1614-0698443

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T16:05:32', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '6e34ad9e-1d4f-4c6d-ad3e-603fc72ece1a'	(b) (4), (b) (6) System	30 Sep 2020 20:05:45
User entered 'No (N)'	System	30 Sep 2020 20:05:45

FDA-CBER-2022-1614-0698444

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T16:05:42', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '6e34ad9e-1d4f-4c6d-ad3e-603fc72ece1a'	System	30 Sep 2020 20:05:45
User entered '30 Sep 2020 16:05'	System	30 Sep 2020 20:05:45

FDA-CBER-2022-1614-0698445

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '30 Sep 2020 16:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698446

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698447

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 2'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698448

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:13:41
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-01T19:57:56', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '36391190-faa8-48a0-998b-51f4ca4aba08'	System	02 Oct 2020 00:00:00
User entered 'Yes (Y)'	System	02 Oct 2020 00:00:00

FDA-CBER-2022-1614-0698449

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:13:41
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-01T19:58:48', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '36391190-faa8-48a0-998b-51f4ca4aba08'	System	02 Oct 2020 00:00:00
User entered '98.9'	System	02 Oct 2020 00:00:00

FDA-CBER-2022-1614-0698450

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:13:41
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-01T19:58:56', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '36391190-faa8-48a0-998b-51f4ca4aba08'	System	02 Oct 2020 00:00:00
User entered 'Yes (Y)'	System	02 Oct 2020 00:00:00

FDA-CBER-2022-1614-0698451

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:13:41
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 18:29:59
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reported medication taken in error.' (Site from System).	Grace Newville (b) (4) (b) (4)	05 Oct 2020 12:46:35
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	02 Oct 2020 00:00:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-01T19:59:13', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '36391190-faa8-48a0-998b-51f4ca4aba08'	System	02 Oct 2020 00:00:00
User entered '1'	System	02 Oct 2020 00:00:00

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:13:41
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-01T19:59:13', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '36391190-faa8-48a0-998b-51f4ca4aba08'	System	02 Oct 2020 00:00:00
User entered '0'	System	02 Oct 2020 00:00:00

FDA-CBER-2022-1614-0698453

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-01T19:59:58', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '36391190-faa8-48a0-998b-51f4ca4aba08'	System	02 Oct 2020 00:00:00
User entered '01 Oct 2020 19:59'	System	02 Oct 2020 00:00:00

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '01 Oct 2020 12:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698455

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '02 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698456

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 3'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698457

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:13:41
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T11:27:00', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '0308c5c0-bca0-4a3c-9224-19bf378ddfa9'	(b) (4), (b) (6) System	03 Oct 2020 15:27:27
User entered 'Yes (Y)'	System	03 Oct 2020 15:27:27

FDA-CBER-2022-1614-0698458

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:13:41
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T11:27:11', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '0308c5c0-bca0-4a3c-9224-19bf378ddfa9'	System	03 Oct 2020 15:27:27
User entered '98.7'	System	03 Oct 2020 15:27:27

FDA-CBER-2022-1614-0698459

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:13:41
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T11:27:20', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '0308c5c0-bca0-4a3c-9224-19bf378ddfa9'	System	03 Oct 2020 15:27:27
User entered 'No (N)'	System	03 Oct 2020 15:27:27

FDA-CBER-2022-1614-0698460

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T11:27:25', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '0308c5c0-bca0-4a3c-9224-19bf378ddfa9'	System	03 Oct 2020 15:27:27
User entered '03 Oct 2020 11:27'	System	03 Oct 2020 15:27:27

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '02 Oct 2020 12:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698462

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '03 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698463

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 4'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698464

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:13:41
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T19:03:31', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'a04cdec9-a9c3-4b16-92d8-17a147ab774e'	(b) (4), (b) (6) System	03 Oct 2020 23:04:00
User entered 'Yes (Y)'	System	03 Oct 2020 23:04:00

FDA-CBER-2022-1614-0698465

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:13:41
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T19:03:40', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'a04cdec9-a9c3-4b16-92d8-17a147ab774e'	System	03 Oct 2020 23:04:00
User entered '97.8'	System	03 Oct 2020 23:04:00

FDA-CBER-2022-1614-0698466

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:13:41
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T19:03:49', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'a04cdec9-a9c3-4b16-92d8-17a147ab774e'	System	03 Oct 2020 23:04:00
User entered 'No (N)'	System	03 Oct 2020 23:04:00

FDA-CBER-2022-1614-0698467

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T19:03:58', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'a04cdec9-a9c3-4b16-92d8-17a147ab774e'	System	03 Oct 2020 23:04:00
User entered '03 Oct 2020 19:03'	System	03 Oct 2020 23:04:00

FDA-CBER-2022-1614-0698468

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '03 Oct 2020 12:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698469

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '04 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698470

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 5'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698471

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:13:41
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-04T18:01:03', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '7e1429e1-7d26-4426-bd1f-396699094c33'	(b) (4), (b) (6) System	04 Oct 2020 22:01:39
User entered 'Yes (Y)'	System	04 Oct 2020 22:01:39

FDA-CBER-2022-1614-0698472

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:13:41
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-04T18:01:21', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '7e1429e1-7d26-4426-bd1f-396699094c33'	System	04 Oct 2020 22:01:39
User entered '98.3'	System	04 Oct 2020 22:01:39

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:13:41
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-04T18:01:28', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '7e1429e1-7d26-4426-bd1f-396699094c33'	System	04 Oct 2020 22:01:39
User entered 'No (N)'	System	04 Oct 2020 22:01:39

FDA-CBER-2022-1614-0698474

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-04T18:01:37', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '7e1429e1-7d26-4426-bd1f-396699094c33'	System	04 Oct 2020 22:01:39
User entered '04 Oct 2020 18:01'	System	04 Oct 2020 22:01:39

FDA-CBER-2022-1614-0698475

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '04 Oct 2020 12:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698476

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '05 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698477

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 6'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698478

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:13:41
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-05T19:42:42', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '9f9e8593-42f5-4809-9ca7-01e592004dfb'	(b) (4), (b) (6) System	05 Oct 2020 23:43:27
User entered 'Yes (Y)'	System	05 Oct 2020 23:43:27

FDA-CBER-2022-1614-0698479

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:13:41
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-05T19:42:51', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '9f9e8593-42f5-4809-9ca7-01e592004dfb'	System	05 Oct 2020 23:43:27
User entered '97.8'	System	05 Oct 2020 23:43:27

FDA-CBER-2022-1614-0698480

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:13:41
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-05T19:42:58', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '9f9e8593-42f5-4809-9ca7-01e592004dfb'	(b) (4), (b) (6) System	05 Oct 2020 23:43:27
User entered 'No (N)'	System	05 Oct 2020 23:43:27

FDA-CBER-2022-1614-0698481

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-05T19:43:25', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '9f9e8593-42f5-4809-9ca7-01e592004dfb'	System	05 Oct 2020 23:43:27
User entered '05 Oct 2020 19:43'	System	05 Oct 2020 23:43:27

FDA-CBER-2022-1614-0698482

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '05 Oct 2020 12:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698483

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '06 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698484

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 7'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698485

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:13:41
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-06T17:53:02', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '70875f47-3e37-4f71-a06a-f02919cc41e3'	(b) (4), (b) (6) System	06 Oct 2020 21:53:29
User entered 'Yes (Y)'	System	06 Oct 2020 21:53:29

FDA-CBER-2022-1614-0698486

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:13:41
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-06T17:53:09', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '70875f47-3e37-4f71-a06a-f02919cc41e3'	System	06 Oct 2020 21:53:29
User entered '98.3'	System	06 Oct 2020 21:53:29

FDA-CBER-2022-1614-0698487

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:13:41
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-06T17:53:16', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '70875f47-3e37-4f71-a06a-f02919cc41e3'	(b) (4), (b) (6) System	06 Oct 2020 21:53:29
User entered 'No (N)'	System	06 Oct 2020 21:53:29

FDA-CBER-2022-1614-0698488

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-06T17:53:26', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '70875f47-3e37-4f71-a06a-f02919cc41e3'	System	06 Oct 2020 21:53:29
User entered '06 Oct 2020 17:53'	System	06 Oct 2020 21:53:29

FDA-CBER-2022-1614-0698489

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '06 Oct 2020 12:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698490

US3242269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '07 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698491

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698492

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T12:49:35', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '97437f5d-ce1e-4032-9cca-1d5bedecbe7a'	(b) (4), (b) (6) System	30 Sep 2020 16:50:10
User entered 'None (1)'	System	30 Sep 2020 16:50:10

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T12:49:40', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '97437f5d-ce1e-4032-9cca-1d5bedecbe7a'	(b) (4), (b) (6) System	30 Sep 2020 16:50:10
User entered 'No (N)'	System	30 Sep 2020 16:50:10

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T12:49:45', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '97437f5d-ce1e-4032-9cca-1d5bedecbe7a'	(b) (4), (b) (6) System	30 Sep 2020 16:50:10
User entered 'No (N)'	System	30 Sep 2020 16:50:10

FDA-CBER-2022-1614-0698495

US3242269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:13:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T12:49:57', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '97437f5d-ce1e-4032-9cca-1d5bedecbe7a'	(b) (4), (b) (6) System	30 Sep 2020 16:50:10
User entered 'None (1)'	System	30 Sep 2020 16:50:10

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T12:50:06', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '97437f5d-ce1e-4032-9cca-1d5bedecbe7a'	System	30 Sep 2020 16:50:10
User entered '30 Sep 2020 12:50'	System	30 Sep 2020 16:50:10

FDA-CBER-2022-1614-0698497

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '30 Sep 2020 12:35'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698498

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '30 Sep 2020 15:05'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698499

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698500

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T16:05:55', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '4c475ae6-6b88-44ea-9056-5babcb4c8aa6'	System	30 Sep 2020 20:07:04
User entered 'None (1)'	System	30 Sep 2020 20:07:04

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T16:06:10', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '4c475ae6-6b88-44ea-9056-5babcb4c8aa6'	System	30 Sep 2020 20:07:04
User entered 'No (N)'	System	30 Sep 2020 20:07:04

FDA-CBER-2022-1614-0698502

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T16:06:34', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '4c475ae6-6b88-44ea-9056-5babcb4c8aa6'	System	30 Sep 2020 20:07:04
User entered 'No (N)'	System	30 Sep 2020 20:07:04

US3242269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:13:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T16:06:44', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '4c475ae6-6b88-44ea-9056-5babcb4c8aa6'	(b) (4), (b) (6) System	30 Sep 2020 20:07:04
User entered 'None (1)'	System	30 Sep 2020 20:07:04

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T16:07:01', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '4c475ae6-6b88-44ea-9056-5babcb4c8aa6'	System	30 Sep 2020 20:07:04
User entered '30 Sep 2020 16:07'	System	30 Sep 2020 20:07:04

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '30 Sep 2020 16:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698506

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698507

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 2'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698508

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:13:41
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-01T20:00:44', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '68e88638-3270-4337-927b-333bed37b0bf'	System	02 Oct 2020 00:01:27
User entered 'None (1)'	System	02 Oct 2020 00:01:27

FDA-CBER-2022-1614-0698509

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:13:41
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-01T20:00:57', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '68e88638-3270-4337-927b-333bed37b0bf'	System	02 Oct 2020 00:01:27
User entered 'No (N)'	System	02 Oct 2020 00:01:27

FDA-CBER-2022-1614-0698510

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:13:41
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-01T20:01:06', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '68e88638-3270-4337-927b-333bed37b0bf'	System	02 Oct 2020 00:01:27
User entered 'No (N)'	System	02 Oct 2020 00:01:27

FDA-CBER-2022-1614-0698511

US3242269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:13:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-01T20:01:14', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '68e88638-3270-4337-927b-333bed37b0bf'	System	02 Oct 2020 00:01:27
User entered 'None (1)'	System	02 Oct 2020 00:01:27

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-01T20:01:25', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '68e88638-3270-4337-927b-333bed37b0bf'	System	02 Oct 2020 00:01:27
User entered '01 Oct 2020 20:01'	System	02 Oct 2020 00:01:27

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '01 Oct 2020 12:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698514

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '02 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698515

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 3'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698516

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:13:41
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T11:27:37', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '90c071d5-28ca-470c-9748-9e5a36671e1d'	System	03 Oct 2020 15:28:17
User entered 'None (1)'	System	03 Oct 2020 15:28:17

FDA-CBER-2022-1614-0698517

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:13:41
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T11:27:42', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '90c071d5-28ca-470c-9748-9e5a36671e1d'	System	03 Oct 2020 15:28:17
User entered 'No (N)'	System	03 Oct 2020 15:28:17

FDA-CBER-2022-1614-0698518

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:13:41
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T11:27:50', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '90c071d5-28ca-470c-9748-9e5a36671e1d'	System	03 Oct 2020 15:28:17
User entered 'No (N)'	System	03 Oct 2020 15:28:17

FDA-CBER-2022-1614-0698519

US3242269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:13:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T11:28:05', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '90c071d5-28ca-470c-9748-9e5a36671e1d'	System	03 Oct 2020 15:28:17
User entered 'None (1)'	System	03 Oct 2020 15:28:17

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T11:28:12', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '90c071d5-28ca-470c-9748-9e5a36671e1d'	System	03 Oct 2020 15:28:17
User entered '03 Oct 2020 11:28'	System	03 Oct 2020 15:28:17

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '02 Oct 2020 12:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698522

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '03 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698523

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 4'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698524

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:13:41
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T19:04:05', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '084c2225-c943-49e0-b359-1b4a5e175614'	System	03 Oct 2020 23:04:49
User entered 'None (1)'	System	03 Oct 2020 23:04:49

FDA-CBER-2022-1614-0698525

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:13:41
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T19:04:09', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '084c2225-c943-49e0-b359-1b4a5e175614'	System	03 Oct 2020 23:04:49
User entered 'No (N)'	System	03 Oct 2020 23:04:49

FDA-CBER-2022-1614-0698526

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:13:41
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T19:04:14', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '084c2225-c943-49e0-b359-1b4a5e175614'	(b) (4), (b) (6) System	03 Oct 2020 23:04:49
User entered 'No (N)'	System	03 Oct 2020 23:04:49

FDA-CBER-2022-1614-0698527

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:13:41
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T19:04:27', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '084c2225-c943-49e0-b359-1b4a5e175614'	(b) (4), (b) (6) System	03 Oct 2020 23:04:49
User entered 'None (1)'	System	03 Oct 2020 23:04:49

FDA-CBER-2022-1614-0698528

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T19:04:33', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '084c2225-c943-49e0-b359-1b4a5e175614'	System	03 Oct 2020 23:04:49
User entered '03 Oct 2020 19:04'	System	03 Oct 2020 23:04:49

FDA-CBER-2022-1614-0698529

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '03 Oct 2020 12:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698530

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '04 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698531

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 5'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698532

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:13:41
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-04T18:01:44', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'ebf9bbde-2b5b-4f05-b2f6-5f2c56be2417'	System	04 Oct 2020 22:02:34
User entered 'None (1)'	System	04 Oct 2020 22:02:34

FDA-CBER-2022-1614-0698533

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:13:41
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-04T18:01:49', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'ebf9bbde-2b5b-4f05-b2f6-5f2c56be2417'	System	04 Oct 2020 22:02:34
User entered 'No (N)'	System	04 Oct 2020 22:02:34

FDA-CBER-2022-1614-0698534

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:13:41
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-04T18:01:54', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'ebf9bbde-2b5b-4f05-b2f6-5f2c56be2417'	System	04 Oct 2020 22:02:34
User entered 'No (N)'	System	04 Oct 2020 22:02:34

FDA-CBER-2022-1614-0698535

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:13:41
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-04T18:02:06', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'ebf9bbde-2b5b-4f05-b2f6-5f2c56be2417'	(b) (4), (b) (6) System	04 Oct 2020 22:02:34
User entered 'None (1)'	System	04 Oct 2020 22:02:34

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-04T18:02:28', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'ebf9bbde-2b5b-4f05-b2f6-5f2c56be2417'	System	04 Oct 2020 22:02:34
User entered '04 Oct 2020 18:02'	System	04 Oct 2020 22:02:34

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '04 Oct 2020 12:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698538

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '05 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698539

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 6'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698540

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:13:41
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-05T19:43:34', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd8349a2e-7048-46d2-9f64-9c8cade6a9c2'	System	05 Oct 2020 23:44:10
User entered 'None (1)'	System	05 Oct 2020 23:44:10

FDA-CBER-2022-1614-0698541

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:13:41
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-05T19:43:41', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd8349a2e-7048-46d2-9f64-9c8cade6a9c2'	System	05 Oct 2020 23:44:10
User entered 'No (N)'	System	05 Oct 2020 23:44:10

FDA-CBER-2022-1614-0698542

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:13:41
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-05T19:43:54', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd8349a2e-7048-46d2-9f64-9c8cade6a9c2'	System	05 Oct 2020 23:44:10
User entered 'No (N)'	System	05 Oct 2020 23:44:10

FDA-CBER-2022-1614-0698543

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:13:41
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-05T19:44:02', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd8349a2e-7048-46d2-9f64-9c8cade6a9c2'	(b) (4), (b) (6) System	05 Oct 2020 23:44:10
User entered 'None (1)'	System	05 Oct 2020 23:44:10

FDA-CBER-2022-1614-0698544

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-05T19:44:08', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd8349a2e-7048-46d2-9f64-9c8cade6a9c2'	System	05 Oct 2020 23:44:10
User entered '05 Oct 2020 19:44'	System	05 Oct 2020 23:44:10

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '05 Oct 2020 12:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698546

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '06 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698547

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 7'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698548

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:13:41
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-06T17:53:43', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'edba304d-abcc-44de-a58b-f658377affd8'	System	06 Oct 2020 21:54:22
User entered 'None (1)'	System	06 Oct 2020 21:54:22

FDA-CBER-2022-1614-0698549

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:13:41
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-06T17:53:50', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'edba304d-abcc-44de-a58b-f658377affd8'	System	06 Oct 2020 21:54:22
User entered 'No (N)'	System	06 Oct 2020 21:54:22

FDA-CBER-2022-1614-0698550

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:13:41
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-06T17:53:58', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'edba304d-abcc-44de-a58b-f658377affd8'	System	06 Oct 2020 21:54:22
User entered 'No (N)'	System	06 Oct 2020 21:54:22

FDA-CBER-2022-1614-0698551

US3242269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:13:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-06T17:54:10', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'edba304d-abcc-44de-a58b-f658377affd8'	System	06 Oct 2020 21:54:22
User entered 'None (1)'	System	06 Oct 2020 21:54:22

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:13:41
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-06T17:54:20', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'edba304d-abcc-44de-a58b-f658377affd8'	System	06 Oct 2020 21:54:22
User entered '06 Oct 2020 17:54'	System	06 Oct 2020 21:54:22

FDA-CBER-2022-1614-0698553

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '06 Oct 2020 12:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698554

US3242269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '07 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698555

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698556

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T12:50:18', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '2f239b32-f4bb-4c1b-ba7a-bcaa9986e8b8'	System	30 Sep 2020 16:51:10
User entered 'None (0)'	System	30 Sep 2020 16:51:10

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T12:50:26', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '2f239b32-f4bb-4c1b-ba7a-bcaa9986e8b8'	System	30 Sep 2020 16:51:10
User entered 'None (0)'	System	30 Sep 2020 16:51:10

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T12:50:33', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '2f239b32-f4bb-4c1b-ba7a-bcaa9986e8b8'	System	30 Sep 2020 16:51:10
User entered 'None (0)'	System	30 Sep 2020 16:51:10

FDA-CBER-2022-1614-0698559

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T12:50:40', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '2f239b32-f4bb-4c1b-ba7a-bcaa9986e8b8'	System	30 Sep 2020 16:51:10
User entered 'None (0)'	System	30 Sep 2020 16:51:10

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T12:50:47', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '2f239b32-f4bb-4c1b-ba7a-bcaa9986e8b8'	System	30 Sep 2020 16:51:10
User entered 'None (0)'	System	30 Sep 2020 16:51:10

FDA-CBER-2022-1614-0698561

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T12:50:52', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '2f239b32-f4bb-4c1b-ba7a-bcaa9986e8b8'	System	30 Sep 2020 16:51:10
User entered 'None (0)'	System	30 Sep 2020 16:51:10

FDA-CBER-2022-1614-0698562

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
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)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T12:51:01', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '2f239b32-f4bb-4c1b-ba7a-bcaa9986e8b8'	(b) (4), (b) (6) System	30 Sep 2020 16:51:10
User entered 'No (N)'	System	30 Sep 2020 16:51:10

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T12:51:07', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '2f239b32-f4bb-4c1b-ba7a-bcaa9986e8b8'	System	30 Sep 2020 16:51:10
User entered '30 Sep 2020 12:51'	System	30 Sep 2020 16:51:10

FDA-CBER-2022-1614-0698564

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '30 Sep 2020 12:35'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698565

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '30 Sep 2020 15:05'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698566

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698567

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T16:07:09', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'a9d2249c-bdaa-4ccb-9a41-c74ae5fb05da'	(b) (4), (b) (6) System	30 Sep 2020 20:08:10
User entered 'None (0)'	System	30 Sep 2020 20:08:10

FDA-CBER-2022-1614-0698568

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T16:07:14', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'a9d2249c-bdaa-4ccb-9a41-c74ae5fb05da'	System	30 Sep 2020 20:08:10
User entered 'None (0)'	System	30 Sep 2020 20:08:10

FDA-CBER-2022-1614-0698569

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T16:07:24', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'a9d2249c-bdaa-4ccb-9a41-c74ae5fb05da'	System	30 Sep 2020 20:08:10
User entered 'None (0)'	System	30 Sep 2020 20:08:10

FDA-CBER-2022-1614-0698570

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T16:07:37', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'a9d2249c-bdaa-4ccb-9a41-c74ae5fb05da'	(b) (4), (b) (6) System	30 Sep 2020 20:08:10
User entered 'None (0)'	System	30 Sep 2020 20:08:10

FDA-CBER-2022-1614-0698571

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T16:07:41', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'a9d2249c-bdaa-4ccb-9a41-c74ae5fb05da'	(b) (4), (b) (6) System	30 Sep 2020 20:08:10
User entered 'None (0)'	System	30 Sep 2020 20:08:10

FDA-CBER-2022-1614-0698572

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T16:07:50', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'a9d2249c-bdaa-4ccb-9a41-c74ae5fb05da'	System	30 Sep 2020 20:08:10
User entered 'None (0)'	System	30 Sep 2020 20:08:10

FDA-CBER-2022-1614-0698573

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
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)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T16:07:58', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'a9d2249c-bdaa-4ccb-9a41-c74ae5fb05da'	(b) (4), (b) (6) System	30 Sep 2020 20:08:10
User entered 'No (N)'	System	30 Sep 2020 20:08:10

FDA-CBER-2022-1614-0698574

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-09-30T16:08:08', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'a9d2249c-bdaa-4ccb-9a41-c74ae5fb05da'	System	30 Sep 2020 20:08:10
User entered '30 Sep 2020 16:08'	System	30 Sep 2020 20:08:10

FDA-CBER-2022-1614-0698575

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '30 Sep 2020 16:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698576

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698577

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 2'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698578

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-01T20:01:42', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd761ba2e-cb9b-4ba8-8781-2d85a0785eaa'	System	02 Oct 2020 00:02:52
User entered 'None (0)'	System	02 Oct 2020 00:02:52

FDA-CBER-2022-1614-0698579

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-01T20:01:46', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd761ba2e-cb9b-4ba8-8781-2d85a0785eaa'	System	02 Oct 2020 00:02:52
User entered 'None (0)'	System	02 Oct 2020 00:02:52

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-01T20:01:51', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd761ba2e-cb9b-4ba8-8781-2d85a0785eaa'	System	02 Oct 2020 00:02:52
User entered 'None (0)'	System	02 Oct 2020 00:02:52

FDA-CBER-2022-1614-0698581

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-01T20:02:03', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd761ba2e-cb9b-4ba8-8781-2d85a0785eaa'	System	02 Oct 2020 00:02:52
User entered 'None (0)'	System	02 Oct 2020 00:02:52

FDA-CBER-2022-1614-0698582

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-01T20:02:13', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd761ba2e-cb9b-4ba8-8781-2d85a0785eaa'	System	02 Oct 2020 00:02:52
User entered 'None (0)'	System	02 Oct 2020 00:02:52

FDA-CBER-2022-1614-0698583

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-01T20:02:22', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd761ba2e-cb9b-4ba8-8781-2d85a0785eaa'	System	02 Oct 2020 00:02:52
User entered 'None (0)'	System	02 Oct 2020 00:02:52

FDA-CBER-2022-1614-0698584

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
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)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-01T20:02:34', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd761ba2e-cb9b-4ba8-8781-2d85a0785eaa'	System	02 Oct 2020 00:02:52
User entered 'No (N)'	System	02 Oct 2020 00:02:52

FDA-CBER-2022-1614-0698585

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-01T20:02:50', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd761ba2e-cb9b-4ba8-8781-2d85a0785eaa'	System	02 Oct 2020 00:02:52
User entered '01 Oct 2020 20:02'	System	02 Oct 2020 00:02:52

FDA-CBER-2022-1614-0698586

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '01 Oct 2020 12:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698587

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '02 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698588

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 3'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698589

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T11:28:29', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '592c038b-809f-44c3-9174-e79d3e87f469'	System	03 Oct 2020 15:29:06
User entered 'None (0)'	System	03 Oct 2020 15:29:06

FDA-CBER-2022-1614-0698590

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T11:28:32', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '592c038b-809f-44c3-9174-e79d3e87f469'	System	03 Oct 2020 15:29:06
User entered 'None (0)'	System	03 Oct 2020 15:29:06

FDA-CBER-2022-1614-0698591

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T11:28:38', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '592c038b-809f-44c3-9174-e79d3e87f469'	System	03 Oct 2020 15:29:06
User entered 'None (0)'	System	03 Oct 2020 15:29:06

FDA-CBER-2022-1614-0698592

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T11:28:44', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '592c038b-809f-44c3-9174-e79d3e87f469'	System	03 Oct 2020 15:29:06
User entered 'None (0)'	System	03 Oct 2020 15:29:06

FDA-CBER-2022-1614-0698593

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T11:28:48', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '592c038b-809f-44c3-9174-e79d3e87f469'	System	03 Oct 2020 15:29:06
User entered 'None (0)'	System	03 Oct 2020 15:29:06

FDA-CBER-2022-1614-0698594

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T11:28:51', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '592c038b-809f-44c3-9174-e79d3e87f469'	System	03 Oct 2020 15:29:06
User entered 'None (0)'	System	03 Oct 2020 15:29:06

FDA-CBER-2022-1614-0698595

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
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)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T11:29:01', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '592c038b-809f-44c3-9174-e79d3e87f469'	(b) (4), (b) (6) System	03 Oct 2020 15:29:06
User entered 'No (N)'	System	03 Oct 2020 15:29:06

FDA-CBER-2022-1614-0698596

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T11:29:04', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '592c038b-809f-44c3-9174-e79d3e87f469'	System	03 Oct 2020 15:29:06
User entered '03 Oct 2020 11:29'	System	03 Oct 2020 15:29:06

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '02 Oct 2020 12:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698598

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '03 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698599

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 4'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698600

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T19:04:41', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '850379c7-1665-4947-ab5e-810edcbf0b0d'	System	03 Oct 2020 23:05:14
User entered 'None (0)'	System	03 Oct 2020 23:05:14

FDA-CBER-2022-1614-0698601

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T19:04:45', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '850379c7-1665-4947-ab5e-810edcbf0b0d'	System	03 Oct 2020 23:05:14
User entered 'None (0)'	System	03 Oct 2020 23:05:14

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T19:04:50', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '850379c7-1665-4947-ab5e-810edcbf0b0d'	System	03 Oct 2020 23:05:14
User entered 'None (0)'	System	03 Oct 2020 23:05:14

FDA-CBER-2022-1614-0698603

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T19:04:54', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '850379c7-1665-4947-ab5e-810edcbf0b0d'	System	03 Oct 2020 23:05:14
User entered 'None (0)'	System	03 Oct 2020 23:05:14

FDA-CBER-2022-1614-0698604

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T19:04:58', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '850379c7-1665-4947-ab5e-810edcbf0b0d'	System	03 Oct 2020 23:05:14
User entered 'None (0)'	System	03 Oct 2020 23:05:14

FDA-CBER-2022-1614-0698605

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T19:05:03', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '850379c7-1665-4947-ab5e-810edcbf0b0d'	System	03 Oct 2020 23:05:14
User entered 'None (0)'	System	03 Oct 2020 23:05:14

FDA-CBER-2022-1614-0698606

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
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)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T19:05:08', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '850379c7-1665-4947-ab5e-810edcbf0b0d'	System	03 Oct 2020 23:05:14
User entered 'No (N)'	System	03 Oct 2020 23:05:14

FDA-CBER-2022-1614-0698607

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-03T19:05:13', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '850379c7-1665-4947-ab5e-810edcbf0b0d'	System	03 Oct 2020 23:05:14
User entered '03 Oct 2020 19:05'	System	03 Oct 2020 23:05:14

FDA-CBER-2022-1614-0698608

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '03 Oct 2020 12:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698609

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '04 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698610

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 5'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698611

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-04T18:02:37', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '1ec642a0-77f3-4eee-9563-b580e3a2aa50'	System	04 Oct 2020 22:03:18
User entered 'None (0)'	System	04 Oct 2020 22:03:18

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-04T18:02:43', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '1ec642a0-77f3-4eee-9563-b580e3a2aa50'	System	04 Oct 2020 22:03:18
User entered 'None (0)'	System	04 Oct 2020 22:03:18

FDA-CBER-2022-1614-0698613

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-04T18:02:47', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '1ec642a0-77f3-4eee-9563-b580e3a2aa50'	System	04 Oct 2020 22:03:18
User entered 'None (0)'	System	04 Oct 2020 22:03:18

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-04T18:02:53', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '1ec642a0-77f3-4eee-9563-b580e3a2aa50'	System	04 Oct 2020 22:03:18
User entered 'None (0)'	System	04 Oct 2020 22:03:18

FDA-CBER-2022-1614-0698615

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-04T18:02:58', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '1ec642a0-77f3-4eee-9563-b580e3a2aa50'	System	04 Oct 2020 22:03:18
User entered 'None (0)'	System	04 Oct 2020 22:03:18

FDA-CBER-2022-1614-0698616

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-04T18:03:03', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '1ec642a0-77f3-4eee-9563-b580e3a2aa50'	System	04 Oct 2020 22:03:18
User entered 'None (0)'	System	04 Oct 2020 22:03:18

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
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) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-04T18:03:09', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '1ec642a0-77f3-4eee-9563-b580e3a2aa50'	System	04 Oct 2020 22:03:18
User entered 'No (N)'	System	04 Oct 2020 22:03:18

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-04T18:03:14', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '1ec642a0-77f3-4eee-9563-b580e3a2aa50'	System	04 Oct 2020 22:03:18
User entered '04 Oct 2020 18:03'	System	04 Oct 2020 22:03:18

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '04 Oct 2020 12:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698620

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '05 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698621

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 6'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698622

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-05T19:44:17', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '6deb7a44-4f91-4f43-ac24-91d22fdab318'	System	05 Oct 2020 23:45:12
User entered 'None (0)'	System	05 Oct 2020 23:45:12

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-05T19:44:20', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '6deb7a44-4f91-4f43-ac24-91d22fdab318'	System	05 Oct 2020 23:45:12
User entered 'None (0)'	System	05 Oct 2020 23:45:12

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-05T19:44:25', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '6deb7a44-4f91-4f43-ac24-91d22fdab318'	System	05 Oct 2020 23:45:12
User entered 'None (0)'	System	05 Oct 2020 23:45:12

FDA-CBER-2022-1614-0698625

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-05T19:44:29', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '6deb7a44-4f91-4f43-ac24-91d22fdab318'	System	05 Oct 2020 23:45:12
User entered 'None (0)'	System	05 Oct 2020 23:45:12

FDA-CBER-2022-1614-0698626

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-05T19:44:34', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '6deb7a44-4f91-4f43-ac24-91d22fdab318'	(b) (4), (b) (6) System	05 Oct 2020 23:45:12
User entered 'None (0)'	System	05 Oct 2020 23:45:12

FDA-CBER-2022-1614-0698627

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-05T19:44:42', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '6deb7a44-4f91-4f43-ac24-91d22fdab318'	System	05 Oct 2020 23:45:12
User entered 'None (0)'	System	05 Oct 2020 23:45:12

FDA-CBER-2022-1614-0698628

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
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)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-05T19:44:50', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '6deb7a44-4f91-4f43-ac24-91d22fdab318'	(b) (4), (b) (6) System	05 Oct 2020 23:45:12
User entered 'No (N)'	System	05 Oct 2020 23:45:12

FDA-CBER-2022-1614-0698629

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-05T19:45:10', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '6deb7a44-4f91-4f43-ac24-91d22fdab318'	System	05 Oct 2020 23:45:12
User entered '05 Oct 2020 19:45'	System	05 Oct 2020 23:45:12

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '05 Oct 2020 12:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698631

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '06 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698632

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	30 Sep 2020 16:17:15
User entered 'Day 7'	System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698633

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-06T17:54:30', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '882269d0-f2ea-49b0-adc2-959d47d75b79'	System	06 Oct 2020 21:56:18
User entered 'None (0)'	System	06 Oct 2020 21:56:18

FDA-CBER-2022-1614-0698634

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-06T17:54:34', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '882269d0-f2ea-49b0-adc2-959d47d75b79'	System	06 Oct 2020 21:56:18
User entered 'None (0)'	System	06 Oct 2020 21:56:18

FDA-CBER-2022-1614-0698635

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-06T17:54:40', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '882269d0-f2ea-49b0-adc2-959d47d75b79'	System	06 Oct 2020 21:56:18
User entered 'None (0)'	System	06 Oct 2020 21:56:18

FDA-CBER-2022-1614-0698636

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-06T17:54:44', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '882269d0-f2ea-49b0-adc2-959d47d75b79'	System	06 Oct 2020 21:56:18
User entered 'None (0)'	System	06 Oct 2020 21:56:18

FDA-CBER-2022-1614-0698637

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-06T17:54:48', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '882269d0-f2ea-49b0-adc2-959d47d75b79'	System	06 Oct 2020 21:56:18
User entered 'None (0)'	System	06 Oct 2020 21:56:18

FDA-CBER-2022-1614-0698638

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-06T17:54:52', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '882269d0-f2ea-49b0-adc2-959d47d75b79'	System	06 Oct 2020 21:56:18
User entered 'None (0)'	System	06 Oct 2020 21:56:18

FDA-CBER-2022-1614-0698639

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
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) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-06T17:55:03', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '882269d0-f2ea-49b0-adc2-959d47d75b79'	System	06 Oct 2020 21:56:18
User entered 'No (N)'	System	06 Oct 2020 21:56:18

FDA-CBER-2022-1614-0698640

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-10-06T17:55:08', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '882269d0-f2ea-49b0-adc2-959d47d75b79'	System	06 Oct 2020 21:56:18
User entered '06 Oct 2020 17:55'	System	06 Oct 2020 21:56:18

FDA-CBER-2022-1614-0698641

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '06 Oct 2020 12:00'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698642

US3242269
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:13:41
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
User entered '07 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 16:17:15

FDA-CBER-2022-1614-0698643

US3242269
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:07:05
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	14 Oct 2020 18:34:35

FDA-CBER-2022-1614-0698644

US3242269
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:07:05
User entered '7 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	14 Oct 2020 18:34:35

FDA-CBER-2022-1614-0698645

US3242269
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:07:05
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4) (b) (4)	14 Oct 2020 18:34:35

FDA-CBER-2022-1614-0698646

US3242269
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:07:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	14 Oct 2020 18:34:35

FDA-CBER-2022-1614-0698647

US3242269
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:07:11
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	14 Oct 2020 18:34:38

FDA-CBER-2022-1614-0698648

US3242269
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	14 Oct 2020 18:34:38

FDA-CBER-2022-1614-0698649

US3242269
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:07:18
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	14 Oct 2020 18:34:49

US3242269
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:07:18
User entered '14 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	14 Oct 2020 18:34:49

US3242269
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:07:18
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4) (b) (4)	14 Oct 2020 18:34:49

FDA-CBER-2022-1614-0698652

US3242269
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:07:18
User entered empty.	Erynn McKinley (b) (4) (b) (4)	14 Oct 2020 18:34:49

FDA-CBER-2022-1614-0698653

US3242269
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:07:23
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	14 Oct 2020 18:34:52

FDA-CBER-2022-1614-0698654

US3242269
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	14 Oct 2020 18:34:52

FDA-CBER-2022-1614-0698655

US3242269
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:07:29
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	21 Oct 2020 17:47:24

FDA-CBER-2022-1614-0698656

US3242269
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:07:29
User entered '21 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	21 Oct 2020 17:47:24

FDA-CBER-2022-1614-0698657

US3242269
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:07:29
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4) (b) (4)	21 Oct 2020 17:47:24

FDA-CBER-2022-1614-0698658

US3242269
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:07:29
User entered empty.	Erynn McKinley (b) (4) (b) (4)	21 Oct 2020 17:47:24

FDA-CBER-2022-1614-0698659

US3242269
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:07:33
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	21 Oct 2020 17:47:30

FDA-CBER-2022-1614-0698660

US3242269
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	System	21 Oct 2020 17:47:30

FDA-CBER-2022-1614-0698661

US3242269
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:13:41
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:23
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Nov 2020 13:36:42

FDA-CBER-2022-1614-0698662

US3242269
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:13:41
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:23
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	13 Nov 2020 13:37:16
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	13 Nov 2020 13:37:16
User entered '28 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	13 Nov 2020 13:37:16
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	13 Nov 2020 13:36:42
User entered '13 Nov 2020'	Donna Toepfer (b) (4)	13 Nov 2020 13:36:42

FDA-CBER-2022-1614-0698663

US3242269
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:13:41
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:23
User entered 'Home (Home)'	Donna Toepfer (b) (4)	13 Nov 2020 13:36:42

US3242269
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:13:41
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'VISIT3'	(b) (4), (b) (6) System	13 Nov 2020 13:36:42

FDA-CBER-2022-1614-0698665

US3242269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:22:05
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:26
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Nov 2020 13:37:45

FDA-CBER-2022-1614-0698666

US3242269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:22:05
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:26
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Nov 2020 13:37:57
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	13 Nov 2020 13:37:57
User entered '28 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	13 Nov 2020 13:37:57
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Nov 2020 13:37:45
User entered '13 Nov 2020'	Donna Toepfer (b) (4)	13 Nov 2020 13:37:45

US3242269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:22:05
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:26
User entered '11:25' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	16 Dec 2020 19:08:34
User entered '11:18'	Donna Toepfer (b) (4)	13 Nov 2020 13:37:45

FDA-CBER-2022-1614-0698668

US3242269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
User entered '28 Oct 2020 11:25'	System	16 Dec 2020 19:08:34
User entered '28 Oct 2020 11:18'	System	13 Nov 2020 13:37:57
User entered '13 Nov 2020 11:18'	System	13 Nov 2020 13:37:45

FDA-CBER-2022-1614-0698669

US3242269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:22:05
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:26
User entered '97.1' F	Donna Toepfer (b) (4)	13 Nov 2020 13:37:45

FDA-CBER-2022-1614-0698670

US3242269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:22:05
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:26
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	13 Nov 2020 13:37:45

FDA-CBER-2022-1614-0698671

US3242269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:22:05
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:26
User entered empty.	Donna Toepfer (b) (4)	13 Nov 2020 13:37:45

FDA-CBER-2022-1614-0698672

US3242269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:22:05
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:26
User entered '78'	Donna Toepfer (b) (4)	13 Nov 2020 13:37:45

FDA-CBER-2022-1614-0698673

US3242269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'bpm'	(b) (4), (b) (6) System	13 Nov 2020 13:37:45

FDA-CBER-2022-1614-0698674

US3242269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:22:05
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:26
User entered '16'	Donna Toepfer (b) (4)	13 Nov 2020 13:37:45

FDA-CBER-2022-1614-0698675

US3242269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'breaths/min'	(b) (4), (b) (6) System	13 Nov 2020 13:37:45

FDA-CBER-2022-1614-0698676

US3242269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:22:05
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:26
User entered '148'	Donna Toepfer (b) (4)	13 Nov 2020 13:37:45

FDA-CBER-2022-1614-0698677

US3242269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
User entered 'mmHg'	System	13 Nov 2020 13:37:45

FDA-CBER-2022-1614-0698678

US3242269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:22:05
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:26
User entered '78'	Donna Toepfer (b) (4)	13 Nov 2020 13:37:45

FDA-CBER-2022-1614-0698679

US3242269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'mmHg'	(b) (4), (b) (6) System	13 Nov 2020 13:37:45

FDA-CBER-2022-1614-0698680

US3242269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698681

US3242269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:13:41
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698682

US3242269
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:13:41
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:31
User entered 'No (N)'	Donna Toepfer (b) (4)	13 Nov 2020 13:38:05

US3242269
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:13:41
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:31
User entered empty.	Donna Toepfer (b) (4)	13 Nov 2020 13:38:05

FDA-CBER-2022-1614-0698684

US3242269
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:13:41
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:35
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Nov 2020 13:38:27

FDA-CBER-2022-1614-0698685

US3242269
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:13:41
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:35
User entered '28 Oct 2020'	Donna Toepfer (b) (4)	13 Nov 2020 13:38:27

FDA-CBER-2022-1614-0698686

US3242269
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:13:41
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:35
User entered '12:05'	Donna Toepfer (b) (4)	13 Nov 2020 13:38:27

FDA-CBER-2022-1614-0698687

US3242269
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:13:41
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '28 Oct 2020 12:05'	(b) (4), (b) (6) System	13 Nov 2020 13:38:27

FDA-CBER-2022-1614-0698688

US3242269
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:39
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Nov 2020 13:38:36

FDA-CBER-2022-1614-0698689

US3242269
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	13 Nov 2020 13:38:36

FDA-CBER-2022-1614-0698690

US3242269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 64'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698691

US3242269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

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) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-11-01T08:06:44', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '4c918af1-785c-452f-872b-569fdf5712f8'	System	01 Nov 2020 13:08:32
User entered 'Yes (Y)'	System	01 Nov 2020 13:08:32

US3242269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-11-01T08:06:54', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '4c918af1-785c-452f-872b-569fdf5712f8'	System	01 Nov 2020 13:08:32
User entered 'No (N)'	System	01 Nov 2020 13:08:32

US3242269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

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) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-11-01T08:07:04', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '4c918af1-785c-452f-872b-569fdf5712f8'	System	01 Nov 2020 13:08:32
User entered 'No (N)'	System	01 Nov 2020 13:08:32

US3242269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

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) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-11-01T08:07:15', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '4c918af1-785c-452f-872b-569fdf5712f8'	System	01 Nov 2020 13:08:32
User entered 'Yes (Y)'	System	01 Nov 2020 13:08:32

US3242269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-11-01T08:07:37', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '4c918af1-785c-452f-872b-569fdf5712f8'	(b) (4), (b) (6) System	01 Nov 2020 13:08:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Nov 2020 13:08:32

US3242269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-11-01T08:08:23', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '4c918af1-785c-452f-872b-569fdf5712f8'	System	01 Nov 2020 13:08:32
User entered '01 Nov 2020 08:08:23'	System	01 Nov 2020 13:08:32

US3242269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698698

US3242269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
Data entry locked.	System	01 Sep 2020 16:47:08
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698699

US3242269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 71'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698700

US3242269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-11-08T19:51:25', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '7f5687d8-c3a5-4f73-9251-30f2fa4c584a'	(b) (4), (b) (6) System	09 Nov 2020 00:52:55
User entered 'No (N)'	System	09 Nov 2020 00:52:55

US3242269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-11-08T19:52:05', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '7f5687d8-c3a5-4f73-9251-30f2fa4c584a'	(b) (4), (b) (6) System	09 Nov 2020 00:52:55
User entered 'Yes (Y)'	System	09 Nov 2020 00:52:55

US3242269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-11-08T19:52:34', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '7f5687d8-c3a5-4f73-9251-30f2fa4c584a'	(b) (4), (b) (6) System	09 Nov 2020 00:52:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Nov 2020 00:52:55

US3242269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-11-08T19:52:47', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '7f5687d8-c3a5-4f73-9251-30f2fa4c584a'	System	09 Nov 2020 00:52:55
User entered '08 Nov 2020 19:52:47'	System	09 Nov 2020 00:52:55

US3242269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698705

US3242269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698706

US3242269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:27:30
Data entry locked.	System	01 Sep 2020 16:47:08
User entered 'Day 78'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698707

US3242269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-11-15T16:16:29', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '239a51ac-6be4-4973-81fc-2efb464f8709'	(b) (4), (b) (6) System	15 Nov 2020 21:16:54
User entered 'No (N)'	System	15 Nov 2020 21:16:54

US3242269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-11-15T16:16:41', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '239a51ac-6be4-4973-81fc-2efb464f8709'	System	15 Nov 2020 21:16:54
User entered 'No (N)'	System	15 Nov 2020 21:16:54

US3242269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-11-15T16:16:50', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '239a51ac-6be4-4973-81fc-2efb464f8709'	System	15 Nov 2020 21:16:54
User entered '15 Nov 2020 16:16:50'	System	15 Nov 2020 21:16:54

US3242269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698711

US3242269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:27:30
	(b) (4), (b) (6)	
Data entry locked.	System	01 Sep 2020 16:47:08
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 16:47:08

FDA-CBER-2022-1614-0698712

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698713

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-11-23T04:00:25', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '389d0e24-ac06-4f0f-8f9c-d2fe45a02ba4'	(b) (4), (b) (6) System	23 Nov 2020 09:00:44
User entered 'No (N)'	System	23 Nov 2020 09:00:44

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-11-23T04:00:32', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '389d0e24-ac06-4f0f-8f9c-d2fe45a02ba4'	(b) (4), (b) (6) System	23 Nov 2020 09:00:44
User entered 'No (N)'	System	23 Nov 2020 09:00:44

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-11-23T04:00:38', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '389d0e24-ac06-4f0f-8f9c-d2fe45a02ba4'	System	23 Nov 2020 09:00:44
User entered '23 Nov 2020 04:00:38'	System	23 Nov 2020 09:00:44

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698717

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698718

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698719

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-11-29T13:30:26', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'ab897591-6615-4bbb-9f0d-40788d99fd2c'	(b) (4), (b) (6) System	29 Nov 2020 18:30:51
User entered 'No (N)'	System	29 Nov 2020 18:30:51

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-11-29T13:30:33', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'ab897591-6615-4bbb-9f0d-40788d99fd2c'	(b) (4), (b) (6) System	29 Nov 2020 18:30:51
User entered 'No (N)'	System	29 Nov 2020 18:30:51

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-11-29T13:30:48', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'ab897591-6615-4bbb-9f0d-40788d99fd2c'	System	29 Nov 2020 18:30:51
User entered '29 Nov 2020 13:30:48'	System	29 Nov 2020 18:30:51

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698723

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698724

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698725

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-12-06T17:40:40', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '5be8ad79-cab3-44e0-853b-3afc31d349ca'	(b) (4), (b) (6) System	06 Dec 2020 22:43:02
User entered 'Yes (Y)'	System	06 Dec 2020 22:43:02

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-12-06T17:40:47', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '5be8ad79-cab3-44e0-853b-3afc31d349ca'	(b) (4), (b) (6) System	06 Dec 2020 22:43:02
User entered 'No (N)'	System	06 Dec 2020 22:43:02

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-12-06T17:41:06', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '5be8ad79-cab3-44e0-853b-3afc31d349ca'	(b) (4), (b) (6) System	06 Dec 2020 22:43:02
User entered 'No (N)'	System	06 Dec 2020 22:43:02

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-12-06T17:41:34', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '5be8ad79-cab3-44e0-853b-3afc31d349ca'	(b) (4), (b) (6) System	06 Dec 2020 22:43:02
User entered 'Yes (Y)'	System	06 Dec 2020 22:43:02

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-12-06T17:42:09', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '5be8ad79-cab3-44e0-853b-3afc31d349ca'	(b) (4), (b) (6) System	06 Dec 2020 22:43:02
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Dec 2020 22:43:02

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-12-06T17:42:48', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '5be8ad79-cab3-44e0-853b-3afc31d349ca'	System	06 Dec 2020 22:43:02
User entered '06 Dec 2020 17:42:48'	System	06 Dec 2020 22:43:02

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698732

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698733

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698734

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-12-12T04:01:49', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '5a1cb0f2-8761-432f-a039-6be0ab810ccc'	(b) (4), (b) (6) System	12 Dec 2020 09:02:10
User entered 'No (N)'	System	12 Dec 2020 09:02:10

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-12-12T04:01:56', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '5a1cb0f2-8761-432f-a039-6be0ab810ccc'	(b) (4), (b) (6) System	12 Dec 2020 09:02:10
User entered 'No (N)'	System	12 Dec 2020 09:02:10

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-12-12T04:02:06', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '5a1cb0f2-8761-432f-a039-6be0ab810ccc'	System	12 Dec 2020 09:02:10
User entered '12 Dec 2020 04:02:06'	System	12 Dec 2020 09:02:10

FDA-CBER-2022-1614-0698737

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698738

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698739

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698740

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Mar 2021 09:33:51
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'subject had follow appt for hepatocellular carcinoma. no further updates' (Site from DM).	Donna Toepfer (b) (4)	27 Feb 2021 19:02:44
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 09:09:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-12-19T03:00:28', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '974e2df1-660b-437b-babf-a4bc0b0f4de3'	System	19 Dec 2020 08:02:39
User entered 'Yes (Y)'	System	19 Dec 2020 08:02:39

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-12-19T03:00:39', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '974e2df1-660b-437b-babf-a4bc0b0f4de3'	(b) (4), (b) (6) System	19 Dec 2020 08:02:39
User entered 'Yes (Y)'	System	19 Dec 2020 08:02:39

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-12-19T03:01:14', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '974e2df1-660b-437b-babf-a4bc0b0f4de3'	(b) (4), (b) (6) System	19 Dec 2020 08:02:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Dec 2020 08:02:39

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-12-19T03:01:31', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '974e2df1-660b-437b-babf-a4bc0b0f4de3'	(b) (4), (b) (6) System	19 Dec 2020 08:02:39
User entered 'No (N)'	System	19 Dec 2020 08:02:39

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-12-19T03:01:45', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '974e2df1-660b-437b-babf-a4bc0b0f4de3'	(b) (4), (b) (6) System	19 Dec 2020 08:02:39
User entered 'Yes (Y)'	System	19 Dec 2020 08:02:39

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-12-19T03:01:56', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '974e2df1-660b-437b-babf-a4bc0b0f4de3'	(b) (4), (b) (6) System	19 Dec 2020 08:02:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Dec 2020 08:02:39

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-12-19T03:02:29', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '974e2df1-660b-437b-babf-a4bc0b0f4de3'	System	19 Dec 2020 08:02:39
User entered '19 Dec 2020 03:02:29'	System	19 Dec 2020 08:02:39

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698748

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698749

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698750

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-12-26T06:41:42', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd6afcbf4-8666-4305-a0c9-e3b25a47cadf'	(b) (4), (b) (6) System	26 Dec 2020 11:42:23
User entered 'No (N)'	System	26 Dec 2020 11:42:23

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-12-26T06:41:59', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd6afcbf4-8666-4305-a0c9-e3b25a47cadf'	(b) (4), (b) (6) System	26 Dec 2020 11:42:23
User entered 'No (N)'	System	26 Dec 2020 11:42:23

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2020-12-26T06:42:20', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd6afcbf4-8666-4305-a0c9-e3b25a47cadf'	System	26 Dec 2020 11:42:23
User entered '26 Dec 2020 06:42:20'	System	26 Dec 2020 11:42:23

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698754

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698755

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698756

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2021-01-02T12:18:07', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '329f5d80-e103-422d-862c-ffd34c963b99'	(b) (4), (b) (6) System	02 Jan 2021 17:18:35
User entered 'No (N)'	System	02 Jan 2021 17:18:35

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2021-01-02T12:18:19', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '329f5d80-e103-422d-862c-ffd34c963b99'	(b) (4), (b) (6) System	02 Jan 2021 17:18:35
User entered 'No (N)'	System	02 Jan 2021 17:18:35

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2021-01-02T12:18:33', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: '329f5d80-e103-422d-862c-ffd34c963b99'	System	02 Jan 2021 17:18:35
User entered '02 Jan 2021 12:18:33'	System	02 Jan 2021 17:18:35

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698760

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698761

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698762

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

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) (b) (4), (b) (6)	26 Apr 2021 18:10:28

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you been exposed to someone with 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) (b) (4), (b) (6)	26 Apr 2021 18:10:28

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Please 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) (b) (4), (b) (6)	26 Apr 2021 18:10:28

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

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) (b) (4), (b) (6)	26 Apr 2021 18:10:28

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698767

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698768

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698769

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698770

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698771

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698772

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698773

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698774

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698775

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698776

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698777

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698778

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698779

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698780

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698781

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698782

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698783

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Please 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) (b) (4), (b) (6)	26 Apr 2021 18:10:28

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

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) (b) (4), (b) (6)	26 Apr 2021 18:10:28

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Please 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) (b) (4), (b) (6)	26 Apr 2021 18:10:28

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698787

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698788

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698789

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698790

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2021-01-15T17:27:08', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd0aa2f28-853d-480c-aa36-ddf23f84bb4d'	(b) (4), (b) (6) System	15 Jan 2021 22:29:19
User entered 'Yes (Y)'	System	15 Jan 2021 22:29:19

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2021-01-15T17:27:16', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd0aa2f28-853d-480c-aa36-ddf23f84bb4d'	(b) (4), (b) (6) System	15 Jan 2021 22:29:19
User entered 'No (N)'	System	15 Jan 2021 22:29:19

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2021-01-15T17:27:26', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd0aa2f28-853d-480c-aa36-ddf23f84bb4d'	(b) (4), (b) (6) System	15 Jan 2021 22:29:19
User entered 'No (N)'	System	15 Jan 2021 22:29:19

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2021-01-15T17:27:52', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd0aa2f28-853d-480c-aa36-ddf23f84bb4d'	(b) (4), (b) (6) System	15 Jan 2021 22:29:19
User entered 'Yes (Y)'	System	15 Jan 2021 22:29:19

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2021-01-15T17:28:20', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd0aa2f28-853d-480c-aa36-ddf23f84bb4d'	(b) (4), (b) (6) System	15 Jan 2021 22:29:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Jan 2021 22:29:19

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EAB09BA-DF4C-4C86-BB70-028455A7FE0A)', Time: '2021-01-15T17:29:07', User OID: 'PatientReportedOutcome (US3242269)', ODM File OID: 'd0aa2f28-853d-480c-aa36-ddf23f84bb4d'	System	15 Jan 2021 22:29:19
User entered '15 Jan 2021 17:29:07'	System	15 Jan 2021 22:29:19

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698797

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698798

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698799

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

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) (b) (4), (b) (6)	26 Apr 2021 18:10:28

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Have you been exposed to someone with 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) (b) (4), (b) (6)	26 Apr 2021 18:10:28

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Please 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) (b) (4), (b) (6)	26 Apr 2021 18:10:28

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

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) (b) (4), (b) (6)	26 Apr 2021 18:10:28

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698804

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698806

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698807

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698808

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698809

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698810

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698811

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698812

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698813

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698814

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698815

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698816

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698817

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698819

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698820

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Please 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) (b) (4), (b) (6)	26 Apr 2021 18:10:28

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

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) (b) (4), (b) (6)	26 Apr 2021 18:10:28

US3242269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:13:41

Please 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) (b) (4), (b) (6)	26 Apr 2021 18:10:28

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698824

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698825

US3242269
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:13:41
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:42:42
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 21:42:42

FDA-CBER-2022-1614-0698826

US3242269
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:06
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	23 Nov 2020 21:53:39

FDA-CBER-2022-1614-0698827

US3242269
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:06
User entered '23 Nov 2020'	Erynn McKinley (b) (4) (b) (4)	23 Nov 2020 21:53:39

FDA-CBER-2022-1614-0698828

US3242269
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:06
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4) (b) (4)	23 Nov 2020 21:53:39

US3242269
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:06
User entered empty.	Erynn McKinley (b) (4) (b) (4)	23 Nov 2020 21:53:39

FDA-CBER-2022-1614-0698830

US3242269
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:05:10
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	23 Nov 2020 21:53:45

US3242269
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	System	23 Nov 2020 21:53:45

FDA-CBER-2022-1614-0698832

US3242269
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:45:48
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	28 Dec 2020 21:49:42

US3242269
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:45:48
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
User entered '28 Dec 2020'	Erynn McKinley (b) (4) (b) (4)	28 Dec 2020 21:49:42

US3242269
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:45:48
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4) (b) (4)	28 Dec 2020 21:49:42

US3242269
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:13:41
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:45:48
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Dec 2020 21:49:42

FDA-CBER-2022-1614-0698836

US3242269
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:45:37
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	28 Dec 2020 21:49:52

FDA-CBER-2022-1614-0698837

US3242269
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:13:41
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	System	28 Dec 2020 21:49:52

FDA-CBER-2022-1614-0698838

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:13:41
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:04:19
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	22 Jan 2021 17:52:34

FDA-CBER-2022-1614-0698839

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:13:41
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:04:19
User entered '22 Jan 2021'	Donna Toepfer (b) (4)	22 Jan 2021 17:52:34

FDA-CBER-2022-1614-0698840

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:13:41
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:04:19
User entered 'Home (Home)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Jan 2021 17:53:25
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	22 Jan 2021 17:52:34

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:13:41
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	22 Jan 2021 17:52:34

FDA-CBER-2022-1614-0698842

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:13:41
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:04:24
User entered '22 Jan 2021'	Donna Toepfer (b) (4)	22 Jan 2021 17:52:51

FDA-CBER-2022-1614-0698843

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:13:41
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 16:07:33
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:48:09

FDA-CBER-2022-1614-0698844

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:13:41
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:04:24
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	22 Jan 2021 17:52:51

FDA-CBER-2022-1614-0698845

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:13:41
Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 16:07:33
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:48:09

FDA-CBER-2022-1614-0698846

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:13:41
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:04:24
User entered '22 Jan 2021'	Donna Toepfer (b) (4)	22 Jan 2021 17:52:51

FDA-CBER-2022-1614-0698847

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:13:41
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:04:24
User entered 'mRNA-1273 (mRNA-1273)'	Donna Toepfer (b) (4)	22 Jan 2021 17:52:51

FDA-CBER-2022-1614-0698848

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:13:41
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:04:24
User entered 'mRNA-1273 (mRNA-1273)'	Donna Toepfer (b) (4)	22 Jan 2021 17:52:51

FDA-CBER-2022-1614-0698849

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:13:41
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:04:24
User entered 'mRNA-1273 (mRNA-1273)'	Donna Toepfer (b) (4)	22 Jan 2021 17:52:51

FDA-CBER-2022-1614-0698850

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:13:41
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:04:24
User entered 'No (N)'	Donna Toepfer (b) (4)	22 Jan 2021 17:52:51

FDA-CBER-2022-1614-0698851

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:13:41
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	22 Jan 2021 17:52:51

FDA-CBER-2022-1614-0698852

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:13:41
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	22 Jan 2021 17:52:51

FDA-CBER-2022-1614-0698853

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:13:41
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:04:30
User entered 'No (N)'	Donna Toepfer (b) (4)	22 Jan 2021 17:53:33

FDA-CBER-2022-1614-0698854

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:13:41
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:04:30
User entered empty.	Donna Toepfer (b) (4)	22 Jan 2021 17:53:33

FDA-CBER-2022-1614-0698855

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:13:41
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:04:30
User entered empty.	Donna Toepfer (b) (4)	22 Jan 2021 17:53:33

FDA-CBER-2022-1614-0698856

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:13:41
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	22 Jan 2021 17:53:33

FDA-CBER-2022-1614-0698857

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 16:13:41
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:04:36
User entered 'No (N)'	Donna Toepfer (b) (4)	22 Jan 2021 17:53:42

FDA-CBER-2022-1614-0698858

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 16:13:41
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:04:36
User entered empty.	Donna Toepfer (b) (4)	22 Jan 2021 17:53:42

FDA-CBER-2022-1614-0698859

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 16:13:41
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:04:36
User entered empty.	Donna Toepfer (b) (4)	22 Jan 2021 17:53:42

FDA-CBER-2022-1614-0698860

US3242269
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 16:13:41
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	22 Jan 2021 17:53:42

FDA-CBER-2022-1614-0698861

US3242269
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 16:13:41
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
DataPoint Un-verified.	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:00:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:00:39
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:12:23
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:28:00

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698863

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Foot fracture, LLT: Fracture of metatarsal bone(s), closed - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 21:46:29
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 21:46:29
Data point term sent to Coder	System	27 Oct 2020 18:02:16
User entered 'Closed fracture of base of 5th metatarsal bone, left foot'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698865

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '2 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698868

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698869

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698870

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
DataPoint Un-verified.	Donna Toepfer (b) (4)	15 Dec 2020 14:10:08
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	15 Dec 2020 14:10:08
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698871

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
DataPoint Un-verified.	Donna Toepfer (b) (4)	15 Dec 2020 14:10:08
User entered '02 Nov 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	15 Dec 2020 14:10:08
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698874

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
DataPoint Un-verified.	Donna Toepfer (b) (4)	15 Dec 2020 14:10:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	15 Dec 2020 14:10:08
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Grade 3/Severe (Grade 3/Severe)'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698875

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698877

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698878

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698879

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698880

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698881

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698882

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698883

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698884

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698885

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698886

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Not Related (NOT RELATED)'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698887

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Not Related (NOT RELATED)'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698888

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'None (NONE)'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698889

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '1'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698890

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698891

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698892

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
DataPoint Un-verified.	Donna Toepfer (b) (4)	15 Dec 2020 14:10:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	15 Dec 2020 14:10:08
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698893

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698895

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
User entered '0'	System	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698896

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	27 Oct 2020 18:02:10

FDA-CBER-2022-1614-0698897

US3242269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:13:41
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698898

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698899

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
User closed query 'Per DM CLR: Please confirm the AE term "ASTHMA EXACERBATION", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "exacerbation" from this event. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:19:04
Query 'Per DM CLR: Please confirm the AE term "ASTHMA EXACERBATION", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "exacerbation" from this event. ' answered with 'updated med hx' (Site from DM).	Donna Toepfer (b) (4)	05 Dec 2020 15:43:52
User opened query 'Per DM CLR: Please confirm the AE term "ASTHMA EXACERBATION", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "exacerbation" from this event. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 23:51:37
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Exacerbation of asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 12:34:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 12:34:52
Data point term sent to Coder	System	30 Oct 2020 12:34:09

FDA-CBER-2022-1614-0698900

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Adverse event

Audit	User	Time (GMT)
User entered 'Asthma Exacerbation'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698902

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698903

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698904

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '15 Oct 2020'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698905

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698906

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698907

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
DataPoint Un-verified.	Donna Toepfer (b) (4)	29 Dec 2020 13:17:25
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	29 Dec 2020 13:17:25
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
DataPoint Un-verified.	Donna Toepfer (b) (4)	29 Dec 2020 13:17:25
User entered '07 Dec 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	29 Dec 2020 13:17:25
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698909

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698910

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698911

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698913

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698914

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698915

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698916

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698917

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698918

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698919

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698920

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698921

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698922

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698923

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698924

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698925

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'None (NONE)'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698926

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	30 Oct 2020 12:33:25
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	30 Oct 2020 12:33:16
User entered '0'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698927

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '1' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Oct 2020 12:33:25
User entered '0'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698928

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698929

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
DataPoint Un-verified.	Donna Toepfer (b) (4)	29 Dec 2020 13:17:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	29 Dec 2020 13:17:25
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698930

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698932

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '0'	(b) (4), (b) (6) System	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698933

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	30 Oct 2020 12:33:16

FDA-CBER-2022-1614-0698934

US3242269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:13:41
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698935

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0698936

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Acute sinusitis, LLT: Acute frontal sinusitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:43:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:43:25
Data point term sent to Coder	System	03 Nov 2020 18:42:43
User entered 'Acute Frontal Sinusitis'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

FDA-CBER-2022-1614-0698937

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '29 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

FDA-CBER-2022-1614-0698942

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	System	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
DataPoint Un-verified.	Donna Toepfer (b) (4)	15 Dec 2020 14:11:10
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	15 Dec 2020 14:11:10
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

FDA-CBER-2022-1614-0698944

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
DataPoint Un-verified.	Donna Toepfer (b) (4)	15 Dec 2020 14:11:10
User entered '06 Nov 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	15 Dec 2020 14:11:10
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

FDA-CBER-2022-1614-0698945

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	System	03 Nov 2020 18:42:09

FDA-CBER-2022-1614-0698947

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

FDA-CBER-2022-1614-0698956

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

FDA-CBER-2022-1614-0698959

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Not Related (NOT RELATED)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Not Related (NOT RELATED)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

FDA-CBER-2022-1614-0698961

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'None (NONE)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '1'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

FDA-CBER-2022-1614-0698964

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

FDA-CBER-2022-1614-0698965

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
DataPoint Un-verified.	Donna Toepfer (b) (4)	15 Dec 2020 14:11:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	15 Dec 2020 14:11:10
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

FDA-CBER-2022-1614-0698966

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '0'	System	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	System	03 Nov 2020 18:42:09

US3242269
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:13:41
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 13:12:30
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 13:12:25
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:26
User entered 'USA-US067-2020-mRNA-1273-P301000019'	System	15 Dec 2020 19:58:18
User entered 'New'	(b) (4), (b) (6)	15 Dec 2020 19:58:18

FDA-CBER-2022-1614-0698972

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Hepatobiliary neoplasms malignant and unspecified, HLT: Hepatic neoplasms malignant, PT: Hepatocellular carcinoma, LLT: Hepatocellular carcinoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 14:10:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 14:10:50
Data point term sent to Coder	System	15 Dec 2020 14:09:35
User entered 'Hepatocellular Carcinoma'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698974

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698975

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered '07 Dec 2020'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698977

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered empty.	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698978

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698979

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698980

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered empty.	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698981

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
User closed query 'PV Query: Please provide the final event end date, when available.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 18:22:53
Query 'PV Query: Please provide the final event end date, when available.' answered with 'subject has withdrawn, AE ongoing at study conclusion' (Site from Safety).	Donna Toepfer (b) (4)	01 Feb 2021 19:00:25
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User opened query 'PV Query: Please provide the final event end date, when available.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 14:28:09
User entered empty.	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698982

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698983

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered 'Grade 4 (Grade 4)'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698985

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered '0'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698986

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered '1'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698987

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered '0'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698988

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered empty.	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698989

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered empty.	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698990

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered empty.	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698991

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered empty.	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698992

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered '0'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698993

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered '0'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698994

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered '0'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698995

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698996

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0698997

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered 'Not Applicable (NOT APPLICABLE)'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:16:47
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 14:55:55
User signature succeeded.	Nathan Segall (b) (4)	22 Feb 2021 13:55:31
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	22 Feb 2021 13:37:11
DataPoint Un-verified.	Donna Toepfer (b) (4)	22 Feb 2021 13:37:02
Signature has been broken.	Donna Toepfer (b) (4)	22 Feb 2021 13:37:02
User entered '0' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Feb 2021 13:37:02
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 12:26:40
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered '1'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0699000

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered '0'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0699001

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:16:47
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 10:35:41
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'liver biopsy noted' (Site from DM).	Donna Toepfer (b) (4)	02 Mar 2021 15:06:25
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 02:27:39
User signature succeeded.	Nathan Segall (b) (4)	22 Feb 2021 13:55:31
DataPoint Un-verified.	Donna Toepfer (b) (4)	22 Feb 2021 13:37:02
Signature has been broken.	Donna Toepfer (b) (4)	22 Feb 2021 13:37:02
User entered '1' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Feb 2021 13:37:02
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered '0'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0699002

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
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)	02 Feb 2021 18:23:21
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 'not available, subject withdrew consent, ongoing at time of withdrawal' (Site from Safety).	Donna Toepfer (b) (4)	01 Feb 2021 19:00:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
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)	22 Dec 2020 14:27:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
User entered empty.	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:16:47
User closed query 'PV Query: Please clarify as last follow up reports subject withdrew consent and after, medical records were sent.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 19:48:25
Query 'PV Query: Please clarify as last follow up reports subject withdrew consent and after, medical records were sent.' answered with 'confirm subject withdrew consent' (Site from Safety).	Donna Toepfer (b) (4)	22 Feb 2021 13:37:19
User opened query 'PV Query: Please clarify as last follow up reports subject withdrew consent and after, medical records were sent.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 16:29:09
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
User closed query 'PV Query: It was mentioned medical records were reviewed. Please send medical records with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:11:34
User closed query 'PV Query: Please confirm if there was any risk factors for hepatocellular carcinoma (eg. chronic viral hepatitis, cirrhosis, heavy alcohol use etc.) ' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:11:28
Query 'PV Query: Please confirm if there was any risk factors for hepatocellular carcinoma (eg. chronic viral hepatitis, cirrhosis, heavy alcohol use etc.) ' answered with 'Unknown' (Site from Safety).	Donna Toepfer (b) (4)	09 Feb 2021 21:13:09
Query 'PV Query: It was mentioned medical records were reviewed. Please send medical records with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Records have been sent' (Site from Safety).	Donna Toepfer (b) (4)	09 Feb 2021 21:12:31

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if there was any risk factors for hepatocellular carcinoma (eg. chronic viral hepatitis, cirrhosis, heavy alcohol use etc.) ' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 17:18:26
User opened query 'PV Query: It was mentioned medical records were reviewed. Please send medical records with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 17:18:16
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)	02 Feb 2021 18:23:52
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please provide the date liver biopsy was performed and its results.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 18:23:31
DataPoint Un-verified.	Donna Toepfer (b) (4)	01 Feb 2021 19:01:38
User entered 'SUBJECT REPORTED IN E-DIARY THAT HE HAD CONTACT WITH A MEDICAL PROVIDER. SUBJECT RECEIVED LIVER BIOPSY. MEDICAL RECORDS RECEIVED AND REVIEWED WITH DIAGNOSIS FOR HEPATOCELLULAR CARCINOMA. WILL FOLLOW SUBJECT FOR PLAN OF TREATMENT. subject withdrew consent, AE ongoing at time of withdrawal.' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Feb 2021 19:01:38

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'not available, subject withdrew consent, ongoing at time of withdrawal' (Site from Safety).	Donna Toepfer (b) (4)	01 Feb 2021 19:01:09
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please provide the date liver biopsy was performed and its results.' answered with 'not available, subject withdrew consent, ongoing at time of withdrawal' (Site from Safety).	Donna Toepfer (b) (4)	01 Feb 2021 19:01:04
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:02
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)	22 Dec 2020 14:27:45
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please provide the date liver biopsy was performed and its results.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 14:27:13
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	15 Dec 2020 14:21:45
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	15 Dec 2020 14:21:45

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Narrative

Audit	User	Time (GMT)
User entered 'Subject reported in e-diary that he had contact with a medical provider. Subject received liver biopsy. Medical records received and reviewed with diagnosis for HEPATOCELLULAR CARCINOMA. Will follow subject for plan of treatment.' reason for change: Data Entry Error	Donna Toepfer (b) (4)	15 Dec 2020 14:21:45
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	15 Dec 2020 14:08:51
User entered empty.	Donna Toepfer (b) (4)	15 Dec 2020 14:08:51

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0699009

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	15 Dec 2020 14:08:51

FDA-CBER-2022-1614-0699010

US3242269
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:13:41
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28

FDA-CBER-2022-1614-0699011

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 09 Jun 2021 16:13:41

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:12:29
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:43:53

FDA-CBER-2022-1614-0699012

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:13:41
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS IC, PRODUCT: FLECAINIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:46:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:46:23
Data point term sent to Coder	System	01 Sep 2020 16:45:15
User entered 'Flecainide Acetate'	Donna Toepfer (b) (4)	01 Sep 2020 16:44:28

FDA-CBER-2022-1614-0699013

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:13:41
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:44:28

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:13:41
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'Atrial Fibrillation'	Donna Toepfer (b) (4)	01 Sep 2020 16:44:28

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:13:41
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered '100'	Donna Toepfer (b) (4)	01 Sep 2020 16:44:28

FDA-CBER-2022-1614-0699016

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:13:41
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'mg (mg)'	Donna Toepfer (b) (4)	01 Sep 2020 16:44:28

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:13:41
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:44:28

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:13:41
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'twice daily (BID)'	Donna Toepfer (b) (4)	01 Sep 2020 16:44:28

FDA-CBER-2022-1614-0699019

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:13:41
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:44:28

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:13:41
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	01 Sep 2020 16:44:28

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:13:41
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:44:28

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:13:41
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'UN UNK 2011'	Donna Toepfer (b) (4)	01 Sep 2020 16:44:28

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:44:28

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:13:41
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:44:28

FDA-CBER-2022-1614-0699025

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:13:41
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:44:28

FDA-CBER-2022-1614-0699026

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:13:41
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:44:28

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:13:41
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
User entered '2'	System	01 Sep 2020 16:44:28

FDA-CBER-2022-1614-0699028

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	01 Sep 2020 16:44:28

FDA-CBER-2022-1614-0699029

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '804 (804)'	(b) (4), (b) (6) System	01 Sep 2020 16:44:28

FDA-CBER-2022-1614-0699030

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:13:41
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:45:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:45:50
Data point term sent to Coder	System	01 Sep 2020 16:45:15
User entered 'Eliquis'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:04

FDA-CBER-2022-1614-0699031

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:13:41
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:04

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:13:41
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'Atrial fibrillation'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:04

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:13:41
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered '5'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:04

FDA-CBER-2022-1614-0699034

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:13:41
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'mg (mg)'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:04

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:13:41
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:45:04

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:13:41
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:04

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:13:41
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:45:04

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:13:41
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:04

FDA-CBER-2022-1614-0699039

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:13:41
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:45:04

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:13:41
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered '01 May 2018'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:04

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:04

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:13:41
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:04

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:13:41
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:45:04

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:13:41
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:04

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:13:41
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	01 Sep 2020 16:45:04

FDA-CBER-2022-1614-0699046

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	01 Sep 2020 16:45:04

FDA-CBER-2022-1614-0699047

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '804 (804)'	(b) (4), (b) (6) System	01 Sep 2020 16:45:04

FDA-CBER-2022-1614-0699048

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:13:41
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:46:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:46:55
Data point term sent to Coder	System	01 Sep 2020 16:46:16
User entered 'Diltiazem'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:27

FDA-CBER-2022-1614-0699049

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:13:41
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:27

FDA-CBER-2022-1614-0699050

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:13:41
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'Hypertension'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:27

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:13:41
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered '180'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:27

FDA-CBER-2022-1614-0699052

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:13:41
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'mg (mg)'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:27

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:13:41
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:45:27

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:13:41
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:27

FDA-CBER-2022-1614-0699055

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:13:41
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:45:27

FDA-CBER-2022-1614-0699056

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:13:41
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:27

FDA-CBER-2022-1614-0699057

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:13:41
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:45:27

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:13:41
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered '1 Jan 2010'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:27

FDA-CBER-2022-1614-0699059

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:27

FDA-CBER-2022-1614-0699060

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:13:41
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:27

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:13:41
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:45:27

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:13:41
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:27

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:13:41
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
	(b) (4), (b) (6)	
User entered '1'	System	01 Sep 2020 16:45:27

FDA-CBER-2022-1614-0699064

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	01 Sep 2020 16:45:27

FDA-CBER-2022-1614-0699065

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '804 (804)'	(b) (4), (b) (6) System	01 Sep 2020 16:45:27

FDA-CBER-2022-1614-0699066

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:13:41
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:46:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:46:57
Data point term sent to Coder	System	01 Sep 2020 16:46:18
User entered 'Simvastatin'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:57

FDA-CBER-2022-1614-0699067

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:13:41
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:57

FDA-CBER-2022-1614-0699068

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:13:41
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'Hypercholesterolemia'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:57

FDA-CBER-2022-1614-0699069

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:13:41
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered '20'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:57

FDA-CBER-2022-1614-0699070

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:13:41
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'mg (mg)'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:57

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:13:41
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:45:57

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:13:41
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:57

FDA-CBER-2022-1614-0699073

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:13:41
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:45:57

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:13:41
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:57

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:13:41
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:45:57

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:13:41
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered '1 Jan 2010'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:57

FDA-CBER-2022-1614-0699077

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:57

FDA-CBER-2022-1614-0699078

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:13:41
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:57

FDA-CBER-2022-1614-0699079

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:13:41
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:45:57

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:13:41
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:45:57

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:13:41
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	01 Sep 2020 16:45:57

FDA-CBER-2022-1614-0699082

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	01 Sep 2020 16:45:57

FDA-CBER-2022-1614-0699083

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '804 (804)'	(b) (4), (b) (6) System	01 Sep 2020 16:45:57

FDA-CBER-2022-1614-0699084

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:13:41
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
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)	01 Sep 2020 16:47:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:47:50
Data point term sent to Coder	System	01 Sep 2020 16:47:20
User entered 'Pantoprazole'	Donna Toepfer (b) (4)	01 Sep 2020 16:46:24

FDA-CBER-2022-1614-0699085

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:13:41
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:46:24

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:13:41
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'Gastroesophageal reflux disease'	Donna Toepfer (b) (4)	01 Sep 2020 16:46:24

FDA-CBER-2022-1614-0699087

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:13:41
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered '40'	Donna Toepfer (b) (4)	01 Sep 2020 16:46:24

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:13:41
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'mg (mg)'	Donna Toepfer (b) (4)	01 Sep 2020 16:46:24

FDA-CBER-2022-1614-0699089

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:13:41
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:46:24

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:13:41
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	01 Sep 2020 16:46:24

FDA-CBER-2022-1614-0699091

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:13:41
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:46:24

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:13:41
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	01 Sep 2020 16:46:24

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:13:41
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:46:24

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:13:41
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered '1 Jan 2017'	Donna Toepfer (b) (4)	01 Sep 2020 16:46:24

FDA-CBER-2022-1614-0699095

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 16:46:24

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:13:41
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Sep 2020 16:46:24

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:13:41
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered empty.	Donna Toepfer (b) (4)	01 Sep 2020 16:46:24

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:13:41
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 20:17:29
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Sep 2020 16:46:24

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:13:41
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	01 Sep 2020 16:46:24

FDA-CBER-2022-1614-0699100

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	01 Sep 2020 16:46:24

FDA-CBER-2022-1614-0699101

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '804 (804)'	(b) (4), (b) (6) System	01 Sep 2020 16:46:24

FDA-CBER-2022-1614-0699102

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:13:41
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE DIHYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 00:48:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 00:48:49
Data point term sent to Coder	System	08 Dec 2020 21:26:14
Coding entries removed.	Donna Toepfer (b) (4)	08 Dec 2020 21:25:34
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE DIHYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 18:04:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 18:04:39
Data point term sent to Coder	System	27 Oct 2020 18:04:19
User entered 'Levocetirizine Dihydrochloride'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:03:44

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:13:41
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:03:44

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:13:41
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:55
User closed query 'Per DM CLR: Please note that the indication provided is unclear. Please spell out the acronym or provide a clear indication for this condition whether MH/AE or prophylactic indication. Reconcile with the most applicable eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 09:41:53
Query 'Per DM CLR: Please note that the indication provided is unclear. Please spell out the acronym or provide a clear indication for this condition whether MH/AE or prophylactic indication. Reconcile with the most applicable eCRF if appropriate. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	08 Dec 2020 21:25:40
DataPoint Un-verified.	Donna Toepfer (b) (4)	08 Dec 2020 21:25:34
User entered 'Seasonal allergic rhinitis' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Dec 2020 21:25:34
User opened query 'Per DM CLR: Please note that the indication provided is unclear. Please spell out the acronym or provide a clear indication for this condition whether MH/AE or prophylactic indication. Reconcile with the most applicable eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 18:31:51
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'SAR'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:03:44

FDA-CBER-2022-1614-0699105

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:13:41
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '5'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:03:44

FDA-CBER-2022-1614-0699106

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:13:41
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:03:44

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:13:41
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:03:44

FDA-CBER-2022-1614-0699108

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:13:41
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'as needed (PRN)'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:03:44

FDA-CBER-2022-1614-0699109

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:13:41
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:03:44

FDA-CBER-2022-1614-0699110

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:13:41
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:03:44

FDA-CBER-2022-1614-0699111

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:13:41
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:03:44

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:13:41
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '15 Sep 2020'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:03:44

FDA-CBER-2022-1614-0699113

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:03:44

FDA-CBER-2022-1614-0699114

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:13:41
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:03:44

FDA-CBER-2022-1614-0699115

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:13:41
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:03:44

FDA-CBER-2022-1614-0699116

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:13:41
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	27 Oct 2020 18:03:44

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:13:41
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	27 Oct 2020 18:03:44

FDA-CBER-2022-1614-0699118

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	27 Oct 2020 18:03:44

FDA-CBER-2022-1614-0699119

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	27 Oct 2020 18:03:44

FDA-CBER-2022-1614-0699120

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:13:41
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 16:21:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 16:21:25
Data point term sent to Coder	System	30 Oct 2020 12:35:09
User entered 'Flonase'	Donna Toepfer (b) (4)	30 Oct 2020 12:34:34

FDA-CBER-2022-1614-0699121

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:13:41
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Donna Toepfer (b) (4)	30 Oct 2020 12:34:34

FDA-CBER-2022-1614-0699122

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:13:41
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Asthma Exacerbation'	Donna Toepfer (b) (4)	30 Oct 2020 12:34:34

FDA-CBER-2022-1614-0699123

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:13:41
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '50'	Donna Toepfer (b) (4)	30 Oct 2020 12:34:34

FDA-CBER-2022-1614-0699124

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:13:41
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'ug (ug)'	Donna Toepfer (b) (4)	30 Oct 2020 12:34:34

FDA-CBER-2022-1614-0699125

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:13:41
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:34:34

FDA-CBER-2022-1614-0699126

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:13:41
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'twice daily (BID)'	Donna Toepfer (b) (4)	30 Oct 2020 12:34:34

FDA-CBER-2022-1614-0699127

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:13:41
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:34:34

FDA-CBER-2022-1614-0699128

US3242269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:13:41

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 09:41:39
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'flonase is a nasal spray' (Site from DM).	Donna Toepfer (b) (4)	08 Dec 2020 21:26:08
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 18:32:23
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Nasal (NASAL)'	Donna Toepfer (b) (4)	30 Oct 2020 12:34:34

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:13:41
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:34:34

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:13:41
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '22 Oct 2020'	Donna Toepfer (b) (4)	30 Oct 2020 12:34:34

FDA-CBER-2022-1614-0699131

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Donna Toepfer (b) (4)	30 Oct 2020 12:34:34

FDA-CBER-2022-1614-0699132

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:13:41
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:55
DataPoint Un-verified.	Donna Toepfer (b) (4)	29 Dec 2020 14:51:14
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	29 Dec 2020 14:51:14
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	30 Oct 2020 12:34:34

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:13:41
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:55
DataPoint Un-verified.	Donna Toepfer (b) (4)	29 Dec 2020 14:51:14
User entered '30 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	29 Dec 2020 14:51:14
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:34:34

FDA-CBER-2022-1614-0699134

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:13:41
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Donna Toepfer (b) (4)	30 Oct 2020 12:34:34

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:13:41
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '2'	(b) (4), (b) (6) System	30 Oct 2020 12:34:34

FDA-CBER-2022-1614-0699136

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	30 Oct 2020 12:34:34

FDA-CBER-2022-1614-0699137

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '804 (804)'	(b) (4), (b) (6) System	30 Oct 2020 12:34:34

FDA-CBER-2022-1614-0699138

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:13:41
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
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: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 12:37:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 12:37:52
Data point term sent to Coder	System	30 Oct 2020 12:37:10
User entered 'Prednisone'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:07

FDA-CBER-2022-1614-0699139

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:13:41
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:07

FDA-CBER-2022-1614-0699140

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:13:41
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Asthma Exacerbation'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:07

FDA-CBER-2022-1614-0699141

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:13:41
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 09:41:24
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'value is correct' (Site from DM).	Donna Toepfer (b) (4)	08 Dec 2020 21:26:30
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 18:32:56
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '4'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:07

FDA-CBER-2022-1614-0699142

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:13:41
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'mg (mg)'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:07

FDA-CBER-2022-1614-0699143

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:13:41
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:37:07

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:13:41
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'other (OTHER)'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:07

FDA-CBER-2022-1614-0699145

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:13:41
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'As directed'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:07

FDA-CBER-2022-1614-0699146

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:13:41
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:07

FDA-CBER-2022-1614-0699147

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:13:41
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:37:07

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:13:41
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '22 Oct 2020'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:07

FDA-CBER-2022-1614-0699149

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:07

FDA-CBER-2022-1614-0699150

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:13:41
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:07

FDA-CBER-2022-1614-0699151

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:13:41
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '28 Oct 2020'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:07

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:13:41
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:07

FDA-CBER-2022-1614-0699153

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:13:41
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	30 Oct 2020 12:37:07

FDA-CBER-2022-1614-0699154

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	30 Oct 2020 12:37:07

FDA-CBER-2022-1614-0699155

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	30 Oct 2020 12:37:07

FDA-CBER-2022-1614-0699156

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:13:41
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 12:38:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 12:38:52
Data point term sent to Coder	System	30 Oct 2020 12:38:13
User entered 'Mucinex'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:48

FDA-CBER-2022-1614-0699157

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:13:41
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:48

FDA-CBER-2022-1614-0699158

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:13:41
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Asthma Exacerbation'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:48

FDA-CBER-2022-1614-0699159

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:13:41
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '1200'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:48

FDA-CBER-2022-1614-0699160

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:13:41
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'mg (mg)'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:48

FDA-CBER-2022-1614-0699161

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:13:41
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:37:48

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:13:41
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:48

FDA-CBER-2022-1614-0699163

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:13:41
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:37:48

FDA-CBER-2022-1614-0699164

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:13:41
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:48

FDA-CBER-2022-1614-0699165

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:13:41
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:37:48

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:13:41
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '22 Oct 2020'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:48

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:48

FDA-CBER-2022-1614-0699168

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:13:41
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:48

FDA-CBER-2022-1614-0699169

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:13:41
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '28 Oct 2020'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:48

FDA-CBER-2022-1614-0699170

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:13:41
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Donna Toepfer (b) (4)	30 Oct 2020 12:37:48

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:13:41
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	30 Oct 2020 12:37:48

FDA-CBER-2022-1614-0699172

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	30 Oct 2020 12:37:48

FDA-CBER-2022-1614-0699173

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '804 (804)'	(b) (4), (b) (6) System	30 Oct 2020 12:37:48

FDA-CBER-2022-1614-0699174

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:13:41
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 21:27:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 21:27:44
Data point term sent to Coder	System	08 Dec 2020 21:27:15
Coding entries removed.	Donna Toepfer (b) (4)	08 Dec 2020 21:26:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 15:37:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 15:37:01
Data point term sent to Coder	System	30 Oct 2020 12:39:14
User entered 'Albuterol'	Donna Toepfer (b) (4)	30 Oct 2020 12:38:41

FDA-CBER-2022-1614-0699175

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:13:41
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Donna Toepfer (b) (4)	30 Oct 2020 12:38:41

FDA-CBER-2022-1614-0699176

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:13:41
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Asthma Exacerbation'	Donna Toepfer (b) (4)	30 Oct 2020 12:38:41

FDA-CBER-2022-1614-0699177

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:13:41
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '90'	Donna Toepfer (b) (4)	30 Oct 2020 12:38:41

FDA-CBER-2022-1614-0699178

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:13:41
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'ug (ug)'	Donna Toepfer (b) (4)	30 Oct 2020 12:38:41

FDA-CBER-2022-1614-0699179

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:13:41
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:38:41

FDA-CBER-2022-1614-0699180

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:13:41
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	30 Oct 2020 12:38:41

FDA-CBER-2022-1614-0699181

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:13:41
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:38:41

FDA-CBER-2022-1614-0699182

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:13:41
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:55
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 09:41:12
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	08 Dec 2020 21:52:39
DataPoint Un-verified.	Donna Toepfer (b) (4)	08 Dec 2020 21:26:50
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Dec 2020 21:26:50
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 18:34:34
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	30 Oct 2020 12:38:41

FDA-CBER-2022-1614-0699183

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:13:41
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:38:41

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:13:41
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '22 Oct 2020'	Donna Toepfer (b) (4)	30 Oct 2020 12:38:41

FDA-CBER-2022-1614-0699185

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Donna Toepfer (b) (4)	30 Oct 2020 12:38:41

FDA-CBER-2022-1614-0699186

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:13:41
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:55
DataPoint Un-verified.	Donna Toepfer (b) (4)	29 Dec 2020 14:34:11
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	29 Dec 2020 14:34:11
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	30 Oct 2020 12:38:41

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:13:41
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:55
DataPoint Un-verified.	Donna Toepfer (b) (4)	29 Dec 2020 14:34:11
User entered '07 Dec 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	29 Dec 2020 14:34:11
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Donna Toepfer (b) (4)	30 Oct 2020 12:38:41

FDA-CBER-2022-1614-0699188

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:13:41
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Donna Toepfer (b) (4)	30 Oct 2020 12:38:41

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:13:41
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	30 Oct 2020 12:38:41

FDA-CBER-2022-1614-0699190

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	30 Oct 2020 12:38:41

FDA-CBER-2022-1614-0699191

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	30 Oct 2020 12:38:41

FDA-CBER-2022-1614-0699192

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:13:41
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
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, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:59:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:59:42
Data point term sent to Coder	System	03 Nov 2020 18:45:51
User entered 'Decadron'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:45:49

FDA-CBER-2022-1614-0699193

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:13:41
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:45:49

FDA-CBER-2022-1614-0699194

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:13:41
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Acute frontal sinusitis'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:45:49

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:13:41
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '8'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:45:49

FDA-CBER-2022-1614-0699196

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:13:41
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:45:49

FDA-CBER-2022-1614-0699197

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:13:41
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:45:49

FDA-CBER-2022-1614-0699198

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:13:41
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'once (ONCE)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:45:49

FDA-CBER-2022-1614-0699199

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:13:41
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:45:49

FDA-CBER-2022-1614-0699200

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:13:41
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Intramuscular (INTRAMUSCULAR)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:45:49

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:13:41
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:45:49

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:13:41
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '31 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:45:49

FDA-CBER-2022-1614-0699203

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:45:49

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:13:41
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:45:49

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:13:41
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '31 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:45:49

FDA-CBER-2022-1614-0699206

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:13:41
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:45:49

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:13:41
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	03 Nov 2020 18:45:49

FDA-CBER-2022-1614-0699208

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	03 Nov 2020 18:45:49

FDA-CBER-2022-1614-0699209

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	03 Nov 2020 18:45:49

FDA-CBER-2022-1614-0699210

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:13:41
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 19:06:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 19:06:24
Data point term sent to Coder	System	03 Nov 2020 18:47:54
User entered 'Rocephin'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:47:04

FDA-CBER-2022-1614-0699211

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:13:41
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:47:04

FDA-CBER-2022-1614-0699212

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:13:41
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Acute frontal sinusitis'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:47:04

FDA-CBER-2022-1614-0699213

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:13:41
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '1000'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:47:04

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:13:41
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:47:04

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:13:41
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:47:04

FDA-CBER-2022-1614-0699216

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:13:41
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'once (ONCE)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:47:04

FDA-CBER-2022-1614-0699217

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:13:41
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:47:04

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:13:41
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Intramuscular (INTRAMUSCULAR)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:47:04

FDA-CBER-2022-1614-0699219

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:13:41
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:47:04

FDA-CBER-2022-1614-0699220

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:13:41
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '31 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:47:04

FDA-CBER-2022-1614-0699221

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:47:04

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:13:41
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:47:04

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:13:41
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '31 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:47:04

FDA-CBER-2022-1614-0699224

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:13:41
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:47:04

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:13:41
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	03 Nov 2020 18:47:04

FDA-CBER-2022-1614-0699226

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	03 Nov 2020 18:47:04

FDA-CBER-2022-1614-0699227

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	03 Nov 2020 18:47:04

FDA-CBER-2022-1614-0699228

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:13:41
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
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, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 19:13:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 19:13:25
Data point term sent to Coder	System	03 Nov 2020 18:48:56
User entered 'Augmentin'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:48:02

FDA-CBER-2022-1614-0699229

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:13:41
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:48:02

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:13:41
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Acute frontal sinusitis'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:48:02

FDA-CBER-2022-1614-0699231

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:13:41
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '875/125'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:48:02

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:13:41
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:48:02

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:13:41
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:48:02

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:13:41
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'twice daily (BID)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:48:02

FDA-CBER-2022-1614-0699235

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:13:41
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:48:02

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:13:41
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:48:02

FDA-CBER-2022-1614-0699237

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:13:41
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:48:02

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:13:41
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '31 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:48:02

FDA-CBER-2022-1614-0699239

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:48:02

FDA-CBER-2022-1614-0699240

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:13:41
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:55
DataPoint Un-verified.	Donna Toepfer (b) (4)	15 Dec 2020 14:17:53
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	15 Dec 2020 14:17:53
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:48:02

FDA-CBER-2022-1614-0699241

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:13:41
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:55
DataPoint Un-verified.	Donna Toepfer (b) (4)	15 Dec 2020 14:17:53
User entered '11 Nov 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	15 Dec 2020 14:17:53
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:48:02

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:13:41
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:48:02

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:13:41
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '2'	(b) (4), (b) (6) System	03 Nov 2020 18:48:02

FDA-CBER-2022-1614-0699244

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	03 Nov 2020 18:48:02

FDA-CBER-2022-1614-0699245

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '804 (804)'	(b) (4), (b) (6) System	03 Nov 2020 18:48:02

FDA-CBER-2022-1614-0699246

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:13:41
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: BROMPHENIRAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: BROMFED DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:50:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:50:23
Data point term sent to Coder	System	03 Nov 2020 18:49:57
User entered 'Bromfed DM'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:49:34

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:13:41
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:49:34

FDA-CBER-2022-1614-0699248

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:13:41
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Acute frontal sinusitis'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:49:34

FDA-CBER-2022-1614-0699249

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:13:41
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '30/2/10'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:49:34

FDA-CBER-2022-1614-0699250

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:13:41
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:49:34

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:13:41
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:49:34

FDA-CBER-2022-1614-0699252

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:13:41
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'other (OTHER)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:49:34

FDA-CBER-2022-1614-0699253

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:13:41
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'every 6 hours'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:49:34

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:13:41
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:49:34

FDA-CBER-2022-1614-0699255

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:13:41
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:49:34

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:13:41
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '31 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:49:34

FDA-CBER-2022-1614-0699257

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:49:34

FDA-CBER-2022-1614-0699258

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:13:41
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:55
DataPoint Un-verified.	Donna Toepfer (b) (4)	15 Dec 2020 14:18:12
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	15 Dec 2020 14:18:12
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:49:34

FDA-CBER-2022-1614-0699259

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:13:41
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:55
DataPoint Un-verified.	Donna Toepfer (b) (4)	15 Dec 2020 14:18:12
User entered '06 Nov 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	15 Dec 2020 14:18:12
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:49:34

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:13:41
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:49:34

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:13:41
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	03 Nov 2020 18:49:34

FDA-CBER-2022-1614-0699262

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	03 Nov 2020 18:49:34

FDA-CBER-2022-1614-0699263

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	03 Nov 2020 18:49:34

FDA-CBER-2022-1614-0699264

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:13:41
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:35:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:35:19
Data point term sent to Coder	System	03 Nov 2020 18:50:59
User entered 'Zithromax'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:50:46

FDA-CBER-2022-1614-0699265

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:13:41
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:50:46

FDA-CBER-2022-1614-0699266

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:13:41
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Acute frontal sinusitis'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:50:46

FDA-CBER-2022-1614-0699267

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:13:41
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '500'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:50:46

FDA-CBER-2022-1614-0699268

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:13:41
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:50:46

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:13:41
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:50:46

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:13:41
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'once (ONCE)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:50:46

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:13:41
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:50:46

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:13:41
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:50:46

FDA-CBER-2022-1614-0699273

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:13:41
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:50:46

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:13:41
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '31 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:50:46

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:50:46

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:13:41
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:50:46

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:13:41
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '31 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:50:46

FDA-CBER-2022-1614-0699278

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:13:41
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:50:46

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:13:41
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	03 Nov 2020 18:50:46

FDA-CBER-2022-1614-0699280

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	03 Nov 2020 18:50:46

FDA-CBER-2022-1614-0699281

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered empty.	(b) (4), (b) (6) System	03 Nov 2020 18:50:46

FDA-CBER-2022-1614-0699282

US3242269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:13:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:35:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:35:19
Data point term sent to Coder	System	03 Nov 2020 18:52:02
User entered 'Zithromax'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:51:54

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:13:41
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:51:54

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:13:41
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Acute frontal sinusitis'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:51:54

FDA-CBER-2022-1614-0699285

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:13:41
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '250'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:51:54

FDA-CBER-2022-1614-0699286

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:13:41
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:51:54

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:13:41
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:51:54

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:13:41
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'once daily (QD)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:51:54

FDA-CBER-2022-1614-0699289

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:13:41
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:51:54

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:13:41
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:51:54

FDA-CBER-2022-1614-0699291

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:13:41
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:51:54

FDA-CBER-2022-1614-0699292

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:13:41
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '01 Nov 2020'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:51:54

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:13:41
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered '0'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:51:54

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:13:41
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:55
DataPoint Un-verified.	Donna Toepfer (b) (4)	15 Dec 2020 14:18:38
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	15 Dec 2020 14:18:38
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:51:54

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:13:41
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:01:55
DataPoint Un-verified.	Donna Toepfer (b) (4)	15 Dec 2020 14:18:38
User entered '04 Nov 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	15 Dec 2020 14:18:38
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:51:54

FDA-CBER-2022-1614-0699296

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:13:41
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:19:04
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Nov 2020 18:51:54

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:13:41
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	03 Nov 2020 18:51:54

FDA-CBER-2022-1614-0699298

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '1'	(b) (4), (b) (6) System	03 Nov 2020 18:51:54

FDA-CBER-2022-1614-0699299

US3242269
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:13:41
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User entered '804 (804)'	(b) (4), (b) (6) System	03 Nov 2020 18:51:54

FDA-CBER-2022-1614-0699300

US3242269
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 09 Jun 2021 16:13:41
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:03:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Dec 2020 14:08:53

US3242269
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 16:13:41
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:03:10
User entered '03 Dec 2020'	Donna Toepfer (b) (4)	15 Dec 2020 14:19:10

FDA-CBER-2022-1614-0699302

US3242269
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 16:13:41
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:03:10
User entered 'Liver biopsy'	Donna Toepfer (b) (4)	15 Dec 2020 14:19:10

FDA-CBER-2022-1614-0699303

US3242269
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 16:13:41
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:03:10
User entered 'Adverse Event (AE)'	Donna Toepfer (b) (4)	15 Dec 2020 14:19:10

FDA-CBER-2022-1614-0699304

US3242269
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 16:13:41
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:03:10
User entered empty.	Donna Toepfer (b) (4)	15 Dec 2020 14:19:10

FDA-CBER-2022-1614-0699305

US3242269
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:13:41
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:03:37
User entered '22 Jan 2021'	Donna Toepfer (b) (4)	22 Jan 2021 18:06:24

FDA-CBER-2022-1614-0699306

US3242269
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:13:41
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Jon Finley (b) (4) (b) (4)	20 Apr 2021 21:22:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:28:52
User closed query 'Per CDM : Per CCGs, relocation should be listed other OTHER as reason for discontinuation. Please verify and amend. Thank you ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:55:58
Query 'Per CDM : Per CCGs, relocation should be listed other OTHER as reason for discontinuation. Please verify and amend. Thank you ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	19 Apr 2021 12:50:07
DataPoint Un-verified.	Donna Toepfer (b) (4)	19 Apr 2021 12:31:24
Signature has been broken.	Donna Toepfer (b) (4)	19 Apr 2021 12:31:24
User entered 'Other (OTHER)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Apr 2021 12:31:24
User opened query 'Per CDM : Per CCGs, relocation should be listed other OTHER as reason for discontinuation. Please verify and amend. Thank you ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 08:59:58
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:03:37
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Donna Toepfer (b) (4)	22 Jan 2021 18:06:24

US3242269

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:13:41

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)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:03:37
User entered 'moved in with son, to far away to participate'	Donna Toepfer (b) (4)	22 Jan 2021 18:06:24

US3242269
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:13:41
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:03:37
User entered empty.	Donna Toepfer (b) (4)	22 Jan 2021 18:06:24

FDA-CBER-2022-1614-0699309

US3242269
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:13:41
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:03:37
User entered empty.	Donna Toepfer (b) (4)	22 Jan 2021 18:06:24

FDA-CBER-2022-1614-0699310

US3242269
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:13:41
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:03:37
User entered empty.	Donna Toepfer (b) (4)	22 Jan 2021 18:06:24

FDA-CBER-2022-1614-0699311

US3242269
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:13:41
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:03:37
User entered empty.	Donna Toepfer (b) (4)	22 Jan 2021 18:06:24

FDA-CBER-2022-1614-0699312

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:50
User entered 'USA-US067-2020-MRNA-1273-P301000019'	System	15 Dec 2020 19:58:18

FDA-CBER-2022-1614-0699313

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'Yes (Y)'	System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'No (N)'	System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'Yes (Y)'	System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'No (N)'	System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'No (N)'	System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'No (N)'	System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'No (N)'	System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered 'Nathan'	System	22 Feb 2021 19:48:44

FDA-CBER-2022-1614-0699321

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered 'Segall'	System	22 Feb 2021 19:48:44

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered '175 country club dr st100a'	System	22 Feb 2021 19:48:44

FDA-CBER-2022-1614-0699323

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered 'Stockbridge'	System	22 Feb 2021 19:48:44

FDA-CBER-2022-1614-0699324

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 21:17:50
User closed query 'Please enter state of site address.(i.e. Georgia).' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 17:25:14
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:24:59
Query 'Please enter state of site address.(i.e. Georgia).' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	03 Apr 2021 12:56:18
User entered 'GA'	Donna Toepfer (b) (4)	03 Apr 2021 12:56:03
User opened query 'Please enter state of site address.(i.e. Georgia).' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 20:44:55

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered '30281'	System	22 Feb 2021 19:48:44

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'US'	System	15 Dec 2020 19:58:48

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
Signature has been broken.	System	22 Feb 2021 19:48:44
User entered '3'	System	22 Feb 2021 19:48:44
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
User entered '2'	System	02 Feb 2021 18:25:24
User entered '1'	System	15 Dec 2020 19:58:48

FDA-CBER-2022-1614-0699328

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:50
User entered 'USA-US067-2020-MRNA-1273-P301000019'	System	15 Dec 2020 19:58:18

FDA-CBER-2022-1614-0699329

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'Yes (Y)'	System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'No (N)'	System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'Yes (Y)'	System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'No (N)'	System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'No (N)'	System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'No (N)'	System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'No (N)'	System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered 'Nathan'	System	22 Feb 2021 19:48:44

FDA-CBER-2022-1614-0699337

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered 'Segall'	System	22 Feb 2021 19:48:44

FDA-CBER-2022-1614-0699338

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered '175 country club dr st100a'	System	22 Feb 2021 19:48:44

FDA-CBER-2022-1614-0699339

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered 'Stockbridge'	System	22 Feb 2021 19:48:44

FDA-CBER-2022-1614-0699340

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 21:17:50
User closed query 'Please enter state of site address.(i.e. Georgia).' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 17:25:14
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:24:59
Query 'Please enter state of site address.(i.e. Georgia).' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	03 Apr 2021 12:56:18
User entered 'GA'	Donna Toepfer (b) (4)	03 Apr 2021 12:56:03
User opened query 'Please enter state of site address.(i.e. Georgia).' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 20:44:55

FDA-CBER-2022-1614-0699341

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered '30281'	System	22 Feb 2021 19:48:44

FDA-CBER-2022-1614-0699342

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'US'	(b) (4), (b) (6) System	15 Dec 2020 19:58:48

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
Signature has been broken.	System	22 Feb 2021 19:48:44
User entered '3'	System	22 Feb 2021 19:48:44
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
User entered '2'	System	02 Feb 2021 18:25:24
User entered '1'	System	15 Dec 2020 19:58:48

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form (1)
Generated On: 09 Jun 2021 16:13:41
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
User entered '15/Dec/2020 13:58'	System	15 Dec 2020 19:58:48

US3242269

Folder: SAE USA-US067-2020-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:13:41

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)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6)	15 Dec 2020 19:58:48

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	15 Dec 2020 19:58:50
User entered 'USA-US067-2020-MRNA-1273-P301000019'	System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Dec 2020 19:58:18

FDA-CBER-2022-1614-0699348

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'No (N)'	(b) (4), (b) (6) System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'No (N)'	(b) (4), (b) (6) System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'No (N)'	(b) (4), (b) (6) System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'No (N)'	(b) (4), (b) (6) System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'No (N)'	(b) (4), (b) (6) System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered 'Nathan'	System	22 Feb 2021 19:48:44

FDA-CBER-2022-1614-0699355

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered 'Segall'	System	22 Feb 2021 19:48:44

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered '175 country club dr st100a'	System	22 Feb 2021 19:48:44

FDA-CBER-2022-1614-0699357

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered 'Stockbridge'	System	22 Feb 2021 19:48:44

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 21:17:50
User closed query 'Please enter state of site address.(i.e. Georgia).' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 17:25:14
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:24:59
Query 'Please enter state of site address.(i.e. Georgia).' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	03 Apr 2021 12:56:18
User entered 'GA'	Donna Toepfer (b) (4)	03 Apr 2021 12:56:03
User opened query 'Please enter state of site address.(i.e. Georgia).' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 20:44:55

FDA-CBER-2022-1614-0699359

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered '30281'	System	22 Feb 2021 19:48:44

FDA-CBER-2022-1614-0699360

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'US'	(b) (4), (b) (6) System	15 Dec 2020 19:58:48

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
Signature has been broken.	System	22 Feb 2021 19:48:44
User entered '3'	System	22 Feb 2021 19:48:44
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
User entered '2'	System	02 Feb 2021 18:25:24
User entered '1'	System	15 Dec 2020 19:58:48

FDA-CBER-2022-1614-0699362

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 16:13:41
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
User entered '02/Feb/2021 13:25'	System	02 Feb 2021 18:25:24

FDA-CBER-2022-1614-0699363

US3242269

Folder: SAE USA-US067-2020-MRNA-1273-P301000019

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:13:41

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)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:25:32
User entered '1'	(b) (4), (b) (6)	02 Feb 2021 18:25:24

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	15 Dec 2020 19:58:50
User entered 'USA-US067-2020-MRNA-1273-P301000019'	System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Dec 2020 19:58:18

FDA-CBER-2022-1614-0699366

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'No (N)'	(b) (4), (b) (6) System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Dec 2020 19:58:18

FDA-CBER-2022-1614-0699368

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'No (N)'	(b) (4), (b) (6) System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'No (N)'	(b) (4), (b) (6) System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'No (N)'	(b) (4), (b) (6) System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'No (N)'	(b) (4), (b) (6) System	15 Dec 2020 19:58:18

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered 'Nathan'	System	22 Feb 2021 19:48:44

FDA-CBER-2022-1614-0699373

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered 'Segall'	System	22 Feb 2021 19:48:44

FDA-CBER-2022-1614-0699374

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered '175 country club dr st100a'	System	22 Feb 2021 19:48:44

FDA-CBER-2022-1614-0699375

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered 'Stockbridge'	System	22 Feb 2021 19:48:44

FDA-CBER-2022-1614-0699376

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 21:17:50
User closed query 'Please enter state of site address.(i.e. Georgia).' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 17:25:14
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:24:59
Query 'Please enter state of site address.(i.e. Georgia).' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	03 Apr 2021 12:56:18
User entered 'GA'	Donna Toepfer (b) (4)	03 Apr 2021 12:56:03
User opened query 'Please enter state of site address.(i.e. Georgia).' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 20:44:55

FDA-CBER-2022-1614-0699377

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered '30281'	System	22 Feb 2021 19:48:44

FDA-CBER-2022-1614-0699378

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:10:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:21:46
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:00:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:58:55
User entered 'US'	(b) (4), (b) (6) System	15 Dec 2020 19:58:48

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form
Generated On: 09 Jun 2021 16:13:41
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
Signature has been broken.	System	22 Feb 2021 19:48:44
User entered '3'	System	22 Feb 2021 19:48:44
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:21:46
User entered '2'	System	02 Feb 2021 18:25:24
User entered '1'	System	15 Dec 2020 19:58:48

FDA-CBER-2022-1614-0699380

US3242269
Folder: SAE USA-US067-2020-MRNA-1273-P301000019
Form: Safety Report Form (3)
Generated On: 09 Jun 2021 16:13:41
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered '22/Feb/2021 14:48'	System	22 Feb 2021 19:48:44

FDA-CBER-2022-1614-0699381

US3242269

Folder: SAE USA-US067-2020-MRNA-1273-P301000019

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:13:41

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)	26 Apr 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	01 Apr 2021 20:43:50
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:42
User entered '1'	(b) (4), (b) (6)	22 Feb 2021 19:48:44