US3032343 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:56:17

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US3032343
Form: Participant Creation
Data signed: (b) (4) **28 Sep 2020 18:21:50**
Generated On: 11 Aug 2021 21:56:17

Participant ID	US3032343

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-0174132

US3032343
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **28 Sep 2020 18:21:50**
Generated On: 11 Aug 2021 21:56:17

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-2022-1614-0174133

US3032343
Folder: Screening
Form: Demographics
Data signed: (b) (4) **28 Sep 2020 18:21:50**
Generated On: 11 Aug 2021 21:56:17

Date of Birth (MMM yyyy)	(b) (6) 1991
Age	29
Age Units	YEARS
Age (Derived)	29
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

US3032343
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **28 Sep 2020 18:21:50**
Generated On: 11 Aug 2021 21:56:17

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-2022-1614-0174135

US3032343
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **28 Sep 2020 18:21:50**
Generated On: 11 Aug 2021 21:56:17

Did the participant meet all eligibility criteria?

Yes ■
No ☐

US3032343
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **28 Sep 2020 18:21:50**
Generated On: 11 Aug 2021 21:56:17

Were any significant conditions reported?	Yes ☐ No ■

FDA-CBER-2022-1614-0174137

US3032343
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **08 Oct 2020 15:57:02**
Generated On: 11 Aug 2021 21:56:17

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	01 SEP 2020
Time of assessment *(00:00-23:59)*	09:25 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 09:25
Height *(xxx.x)*	160.0 cm
Weight *(xxx.x)*	68.4 kg
BMI *(xxx.x)*	26.71875 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-2022-1614-0174138

US3032343
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **28 Sep 2020 18:21:50**
Generated On: 11 Aug 2021 21:56:17

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	01 SEP 2020

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

FDA-CBER-2022-1614-0174139

US3032343
Folder: Screening
Form: Childbearing Potential
Data signed: (b) (4) **28 Sep 2020 18:21:50**
Generated On: 11 Aug 2021 21:56:17

Date of assessment *(dd MMM yyyy)*	01 SEP 2020
Is the participant of childbearing potential?	Yes ■ No ☐
If No, what is the reason?	Surgically sterile ☐ Post-menopausal ☐ Partner medically sterile ☐ Not reached age of Menarche ☐ Other ☐
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	False

FDA-CBER-2022-1614-0174140

US3032343
Folder: Screening
Form: Pregnancy Test
Data signed: (b) (4) **28 Sep 2020 18:21:50**
Generated On: 11 Aug 2021 21:56:17

Was the pregnancy test performed?	Yes ■ No ☐
Date of test *(dd MMM yyyy)*	01 SEP 2020
Test performed	Urine ■ Serum ☐
Result	Positive ☐ Negative ■
Was FSH sample collected?	Yes ☐ No ■
Collection date	
Collection time	
Collection date and time (derived)	

FDA-CBER-2022-1614-0174141

US3032343
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **28 Sep 2020 18:21:50**
Generated On: 11 Aug 2021 21:56:17

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

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

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

US3032343
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **28 Sep 2020 18:21:50**
Generated On: 11 Aug 2021 21:56:17

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	VISIT1

FDA-CBER-2022-1614-0174144

US3032343
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **02 Nov 2020 22:28:15**
Generated On: 11 Aug 2021 21:56:17

What was the date of randomization? *(dd MMM yyyy)*	01 SEP 2020
What was the participant's randomization number?	108996
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-2022-1614-0174145

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **14 Oct 2020 19:48:36**
Generated On: 11 Aug 2021 21:56:17

Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-0174146

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **14 Oct 2020 19:48:36**
Generated On: 11 Aug 2021 21:56:17

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)*	01 SEP 2020
Time of assessment *(00:00-23:59)*	09:25 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 09:25
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	83 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0174147

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **14 Oct 2020 19:48:36**
Generated On: 11 Aug 2021 21:56:17

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)*	01 SEP 2020
Time of assessment *(00:00-23:59)*	11:58 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 11:58
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	64 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	87 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0174148

US3032343
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **28 Sep 2020 18:21:50**
Generated On: 11 Aug 2021 21:56:17

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	01 SEP 2020

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

US3032343
Folder: Visit 1 Day 1
Form: Pregnancy Test
Data signed: (b) (4) **28 Sep 2020 18:21:50**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174150

US3032343
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **28 Sep 2020 18:21:50**
Generated On: 11 Aug 2021 21:56:17

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)*	11:21 (24 HR)
Treatment Date and Time (derived)	1 SEP 2020 11:21
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-2022-1614-0174151

US3032343
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **28 Sep 2020 18:21:50**
Generated On: 11 Aug 2021 21:56:17

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	01 SEP 2020
Collection time *(00:00-23:59)*	10:34 (24 HR)
Collection date and time (derived)	01 SEP 2020 10:34

US3032343
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **08 Dec 2020 19:50:50**
Generated On: 11 Aug 2021 21:56:17

Collection date *(dd MMM yyyy)*			01 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:45	01 SEP 2020 09:45
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0174153

US3032343
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **28 Sep 2020 18:21:50**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174154

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**	97.3 °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	01 SEP 2020 11:57
PC Open Date & Time	01 SEP 2020 11:41
PC Close Date & Time	01 SEP 2020 14:11

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**	98.7 °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 15:56
PC Open Date & Time	01 SEP 2020 15:06
PC Close Date & Time	02 SEP 2020 11:59

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:56:17

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	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	02 SEP 2020 12:11
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:56:17

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**	98.9 °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	03 SEP 2020 12:00
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:56:17

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**	98.9 °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	04 SEP 2020 12:00
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:56:17

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**	99.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	05 SEP 2020 12:49
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:56:17

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**	98.9 °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	06 SEP 2020 12:00
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

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**	98.9 °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	07 SEP 2020 13:05
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:56:17

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 11:58
PC Open Date & Time	01 SEP 2020 11:41
PC Close Date & Time	01 SEP 2020 14:11

FDA-CBER-2022-1614-0174163

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:56:17

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 15:56
PC Open Date & Time	01 SEP 2020 15:06
PC Close Date & Time	02 SEP 2020 11:59

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174165

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:56:17

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 12:01
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-0174166

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:56:17

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 12:01
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:56:17

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 12:49
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-0174168

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:56:17

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

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:56:17

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	07 SEP 2020 13:05
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-0174170

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 ☐

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	01 SEP 2020 11:58
PC Open Date & Time	01 SEP 2020 11:41
PC Close Date & Time	01 SEP 2020 14:11

FDA-CBER-2022-1614-0174172

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 ☐

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	01 SEP 2020 15:57
PC Open Date & Time	01 SEP 2020 15:06
PC Close Date & Time	02 SEP 2020 11:59

FDA-CBER-2022-1614-0174174

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 ■

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17

	Yes ☐
PC Time stamp	02 SEP 2020 12:13
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

FDA-CBER-2022-1614-0174176

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 ■

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17

	Yes
PC Time stamp	03 SEP 2020 12:01
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

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 ■

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17

	Yes
PC Time stamp	04 SEP 2020 12:01
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 ■

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17

	Yes
PC Time stamp	05 SEP 2020 12:50
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-0174182

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 ■

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17

	Yes
PC Time stamp	06 SEP 2020 12:01
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

FDA-CBER-2022-1614-0174184

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 ■

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17

	Yes ☐
PC Time stamp	07 SEP 2020 13:06
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-0174186

US3032343
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **28 Sep 2020 18:21:50**
Generated On: 11 Aug 2021 21:56:17

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	08 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3032343
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **28 Sep 2020 18:21:50**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174188

US3032343
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **08 Dec 2020 19:50:50**
Generated On: 11 Aug 2021 21:56:17

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 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-2022-1614-0174189

US3032343
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **29 Sep 2020 18:38:01**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174190

US3032343
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **29 Sep 2020 18:38:01**
Generated On: 11 Aug 2021 21:56:17

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	22 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0174191

US3032343
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **29 Sep 2020 18:38:01**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174192

US3032343
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **29 Sep 2020 18:38:01**
Generated On: 11 Aug 2021 21:56:17

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-0174193

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **29 Sep 2020 18:38:01**
Generated On: 11 Aug 2021 21:56:17

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	29 SEP 2020
Time of assessment *(00:00-23:59)*	08:20 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 08:20
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	85 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	90 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	66 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0174194

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **29 Sep 2020 18:38:01**
Generated On: 11 Aug 2021 21:56:17

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	29 SEP 2020
Time of assessment *(00:00-23:59)*	10:18 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 10:18
Temperature *(xxx.x)*	36.4 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	93 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	60 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0174195

US3032343
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **29 Sep 2020 18:38:01**
Generated On: 11 Aug 2021 21:56:17

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

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

FDA-CBER-2022-1614-0174196

US3032343
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Data signed: (b) (4) **29 Sep 2020 18:38:01**
Generated On: 11 Aug 2021 21:56:17

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

US3032343
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **29 Sep 2020 18:38:01**
Generated On: 11 Aug 2021 21:56:17

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	29 SEP 2020
What was the treatment time? *(00:00-23:59)*	09:43 (24 HR)
Treatment Date and Time (derived)	29 SEP 2020 09:43
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-2022-1614-0174198

US3032343
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **29 Sep 2020 18:38:01**
Generated On: 11 Aug 2021 21:56:17

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	29 SEP 2020
Collection time *(00:00-23:59)*	08:52 (24 HR)
Collection date and time (derived)	29 SEP 2020 08:52

FDA-CBER-2022-1614-0174199

US3032343
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **29 Sep 2020 18:38:01**
Generated On: 11 Aug 2021 21:56:17

Collection date *(dd MMM yyyy)*			29 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:42	29 SEP 2020 08:42
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0174200

US3032343
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **29 Sep 2020 18:38:01**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174201

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**	97.5 °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	29 SEP 2020 10:19
PC Open Date & Time	29 SEP 2020 10:03
PC Close Date & Time	29 SEP 2020 12:33

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**	98.5 °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	29 SEP 2020 13:34
PC Open Date & Time	29 SEP 2020 13:28
PC Close Date & Time	30 SEP 2020 11:59

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:56:17

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**	99.7 °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	30 SEP 2020 12:12
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

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**	99.8 °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	01 OCT 2020 12:00
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

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**	97.9 °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	02 OCT 2020 13:17
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 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**	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	03 OCT 2020 12:47
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:56:17

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**	97.9 °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	04 OCT 2020 14:20
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

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**	98.6 °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	05 OCT 2020 12:00
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	29 SEP 2020 10:19
PC Open Date & Time	29 SEP 2020 10:03
PC Close Date & Time	29 SEP 2020 12:33

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:56:17

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	29 SEP 2020 13:34
PC Open Date & Time	29 SEP 2020 13:28
PC Close Date & Time	30 SEP 2020 11:59

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	30 SEP 2020 12:12
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	01 OCT 2020 12:01
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	02 OCT 2020 13:17
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:56:17

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	03 OCT 2020 12:47
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	04 OCT 2020 14:20
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	05 OCT 2020 12:00
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 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 ☐

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	29 SEP 2020 10:19
PC Open Date & Time	29 SEP 2020 10:03
PC Close Date & Time	29 SEP 2020 12:33

FDA-CBER-2022-1614-0174219

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 ☐

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	29 SEP 2020 13:35
PC Open Date & Time	29 SEP 2020 13:28
PC Close Date & Time	30 SEP 2020 11:59

FDA-CBER-2022-1614-0174221

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17

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-2022-1614-0174222

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17

	Yes ☐
PC Time stamp	30 SEP 2020 12:13
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

FDA-CBER-2022-1614-0174223

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17

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 ■

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17

	Yes
PC Time stamp	01 OCT 2020 12:03
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

FDA-CBER-2022-1614-0174225

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 ■

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17

	Yes
PC Time stamp	02 OCT 2020 13:18
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

FDA-CBER-2022-1614-0174227

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17

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 ■

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17

	Yes
PC Time stamp	03 OCT 2020 12:47
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17

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 ■

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17

	Yes
PC Time stamp	04 OCT 2020 14:21
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17

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 ■

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17

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

US3032343
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **08 Oct 2020 15:57:02**
Generated On: 11 Aug 2021 21:56:17

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	06 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-2022-1614-0174234

US3032343
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **08 Oct 2020 15:57:02**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174235

US3032343
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **14 Oct 2020 19:48:36**
Generated On: 11 Aug 2021 21:56:17

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	13 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0174236

US3032343
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **14 Oct 2020 19:48:36**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174237

US3032343
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **28 Oct 2020 16:46:59**
Generated On: 11 Aug 2021 21:56:17

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	22 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3032343
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **22 Oct 2020 15:09:15**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174239

US3032343
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **28 Oct 2020 16:46:59**
Generated On: 11 Aug 2021 21:56:17

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	27 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-0174240

US3032343
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **28 Oct 2020 16:46:59**
Generated On: 11 Aug 2021 21:56:17

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	27 OCT 2020
Time of assessment *(00:00-23:59)*	08:30 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 08:30
Temperature *(xxx.x)*	37.1 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	91 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	90 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0174241

US3032343
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **28 Oct 2020 16:46:59**
Generated On: 11 Aug 2021 21:56:17

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	27 OCT 2020

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

FDA-CBER-2022-1614-0174242

US3032343
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **28 Oct 2020 16:46:59**
Generated On: 11 Aug 2021 21:56:17

Was the sample collected?	Yes ☒ No ☐
Collection date *(dd MMM yyyy)*	27 OCT 2020
Collection time *(00:00-23:59)*	08:37 (24 HR)
Collection date and time (derived)	27 OCT 2020 08:37

FDA-CBER-2022-1614-0174243

US3032343
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **28 Oct 2020 16:46:59**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174244

US3032343
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 NOV 2020 00:12:12
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

FDA-CBER-2022-1614-0174245

US3032343
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 NOV 2020 16:59:50
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3032343
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

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 00:46:24
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

FDA-CBER-2022-1614-0174247

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

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	22 NOV 2020 09:19:22
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

FDA-CBER-2022-1614-0174248

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

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	26 NOV 2020 00:17:38
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

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 ☐
Date and time of submission	04 DEC 2020 06:28:13
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

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	10 DEC 2020 01:32:55
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

FDA-CBER-2022-1614-0174251

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 00:14:11
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

FDA-CBER-2022-1614-0174252

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

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	24 DEC 2020 00:02:37
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

FDA-CBER-2022-1614-0174253

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

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	31 DEC 2020 00:41:25
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 00:13:51
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 00:01:53
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

FDA-CBER-2022-1614-0174256

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 JAN 2021 00:34:56
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

FDA-CBER-2022-1614-0174257

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 JAN 2021 01:59:23
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

FDA-CBER-2022-1614-0174258

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 00:53:40
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 00:24:28
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 00:21:58
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 FEB 2021 06:30:07
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 00:23:19
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

FDA-CBER-2022-1614-0174263

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 MAR 2021 00:44:00
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 MAR 2021 00:02:19
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

FDA-CBER-2022-1614-0174265

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 MAR 2021 19:49:27
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3032343
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 11 Aug 2021 21:56:17

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		04 MAR 2021 00:23:33

FDA-CBER-2022-1614-0174267

US3032343
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **06 Apr 2021 15:47:44**
Generated On: 11 Aug 2021 21:56:17

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	25 NOV 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3032343
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **18 Jan 2021 19:32:09**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174269

US3032343
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **06 Apr 2021 15:47:44**
Generated On: 11 Aug 2021 21:56:17

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*	SUBJECT CONTACTED SITE 11JAN2021 TO FINISH SAFETY CALL. NO CHANGES WITH SUBJECT.

US3032343
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **18 Jan 2021 19:32:09**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174271

US3032343
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **06 Apr 2021 15:47:44**
Generated On: 11 Aug 2021 21:56:17

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	29 JAN 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0174272

US3032343
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **18 Mar 2021 21:48:30**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174273

US3032343
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **18 Mar 2021 21:48:30**
Generated On: 11 Aug 2021 21:56:17

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	23 FEB 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0174274

US3032343
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **18 Mar 2021 21:48:30**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174275

US3032343
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **06 Apr 2021 15:47:44**
Generated On: 11 Aug 2021 21:56:17

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT4

FDA-CBER-2022-1614-0174276

US3032343
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **06 Apr 2021 15:47:44**
Generated On: 11 Aug 2021 21:56:17

Were vital signs assessed?	Yes ☐ No ■
Date of assessment *(dd MMM yyyy)*	
Time of assessment *(00:00-23:59)*	
Vital Signs Date and Time (derived)	
Temperature *(xxx.x)*	
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	
Pulse units	
Respiratory Rate *(xxx)*	
Respiratory Rate units	
Systolic Blood Pressure *(xxx)*	
Systolic Blood Pressure units	
Diastolic Blood Pressure *(xxx)*	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0174277

US3032343
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Data signed: (b) (4) **06 Apr 2021 15:47:44**
Generated On: 11 Aug 2021 21:56:17

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.

US3032343
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **06 Apr 2021 15:47:44**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174279

US3032343
Folder: Visit 4 Day 209 (1)
Form: Continuing
Data signed: (b) (4) **06 Apr 2021 15:47:44**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174280

US3032343
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 11 Aug 2021 21:56:17

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-2022-1614-0174281

US3032343
Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Generated On: 11 Aug 2021 21:56:17

Generate Next COVID-19 Assessment	Yes ☐ No ☐

FDA-CBER-2022-1614-0174282

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection
Data signed: (b) (4) **06 Apr 2021 15:47:43**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174283

US3032343
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Data signed: (b) (4) **06 Apr 2021 15:47:43**
Generated On: 11 Aug 2021 21:56:17

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SICKD1

FDA-CBER-2022-1614-0174284

US3032343
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Data signed: (b) (4) **06 Apr 2021 15:47:43**
Generated On: 11 Aug 2021 21:56:17

Were vital signs assessed?	Yes ☐ No ■
Date of assessment *(dd MMM yyyy)*	
Time of assessment *(00:00-23:59)*	
Vital Signs Date and Time (derived)	
Height *(xxx.x)*	
Weight *(xxx.x)*	
Temperature *(xxx.x)*	
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	
Pulse units	
Respiratory Rate *(xxx)*	
Respiratory Rate units	
Systolic Blood Pressure *(xxx)*	
Systolic Blood Pressure units	
Diastolic Blood Pressure *(xxx)*	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0174285

US3032343
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Data signed: (b) (4) **06 Apr 2021 15:47:43**
Generated On: 11 Aug 2021 21:56:17

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.

US3032343
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **06 Apr 2021 15:47:43**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174287

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Data signed: (b) (4) **06 Apr 2021 15:47:43**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174288

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Data signed: (b) (4) **06 Apr 2021 15:47:43**
Generated On: 11 Aug 2021 21:56:17

Were vital signs assessed?	Yes ☐ No ■
Date of assessment *(dd MMM yyyy)*	
Time of assessment *(00:00-23:59)*	
Vital Signs Date and Time (derived)	
Temperature *(xxx.x)*	
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	
Pulse units	
Respiratory Rate *(xxx)*	
Respiratory Rate units	
Systolic Blood Pressure *(xxx)*	
Systolic Blood Pressure units	
Diastolic Blood Pressure *(xxx)*	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Data signed: (b) (4) **06 Apr 2021 15:47:43**
Generated On: 11 Aug 2021 21:56:17

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.

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **06 Apr 2021 15:47:43**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174291

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **06 Apr 2021 15:47:44**
Generated On: 11 Aug 2021 21:56:17

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

FDA-CBER-2022-1614-0174292

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **06 Apr 2021 15:47:44**
Generated On: 11 Aug 2021 21:56:17

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

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **06 Apr 2021 15:47:44**
Generated On: 11 Aug 2021 21:56:17

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	23 FEB 2021
Collection time *(00:00-23:59)*	09:30 (24 HR)
Collection date and time (derived)	23 FEB 2021 09:30

FDA-CBER-2022-1614-0174294

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **06 Apr 2021 15:47:44**
Generated On: 11 Aug 2021 21:56:17

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	23 FEB 2021
Collection time *(00:00 - 23:59)*	09:37
Collection Date and Time (derived)	23 FEB 2021 09:37

US3032343
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **06 Apr 2021 15:47:43**
Generated On: 11 Aug 2021 21:56:17

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

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-0174296

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **06 Apr 2021 15:47:43**
Generated On: 11 Aug 2021 21:56:17

AEID	
Adverse event	SORE THROAT
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)*	24 MAR 2021
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	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)	

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **28 Sep 2020 18:21:50**
Generated On: 11 Aug 2021 21:56:17

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

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

FDA-CBER-2022-1614-0174299

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **06 Apr 2021 15:47:43**
Generated On: 11 Aug 2021 21:56:17

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ■
Indication	PAIN AT INJECTION SITE
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)*	02 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	02 SEP 2020
Was this medication taken for solicited event?	Yes ■ No ☐
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **06 Apr 2021 15:47:43**
Generated On: 11 Aug 2021 21:56:17

Name of Medication	AMOXICILLIN
Prophylaxis	Yes ☐ No ■
Indication	SORE THROAT
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)*	24 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3032343
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **28 Sep 2020 18:21:50**
Generated On: 11 Aug 2021 21:56:17

Were any concomitant procedures performed?	Yes ☐ No ■

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-0174304

US3032343
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **06 Apr 2021 15:47:43**
Generated On: 11 Aug 2021 21:56:17

Date of study discontinuation/completion *(dd MMM yyyy)*	30 MAR 2021
Reason for discontinuation	AE (specify) ☐ SAE (specify) ☐ Complete ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ■ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	SUBJECT IS MOVING OUT OF STATE AND CAN NOT MAKE THE REST OF HER VISITS. SHE DECIDED TO WITHDRAW CONSENT.
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-2022-1614-0174305

Audit

US3032343 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

US3032343
Form: Participant Creation
Generated On: 11 Aug 2021 21:56:17
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
DataPoint Verified.		14 Apr 2021 15:53:41
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'US3032343'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:34:54

FDA-CBER-2022-1614-0174307

US3032343
Form: Participant Creation
Generated On: 11 Aug 2021 21:56:17

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25

FDA-CBER-2022-1614-0174308

US3032343
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	01 Sep 2020 16:27:05

FDA-CBER-2022-1614-0174309

US3032343
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:34:55

FDA-CBER-2022-1614-0174310

US3032343
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4) (b) (4)	01 Sep 2020 16:27:05

FDA-CBER-2022-1614-0174311

US3032343
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'SCRN'	System	01 Sep 2020 16:27:05

FDA-CBER-2022-1614-0174312

US3032343
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:56:17
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered (b) (6) 1991'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:34:56

FDA-CBER-2022-1614-0174313

US3032343
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:56:17
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '29'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:17:32

FDA-CBER-2022-1614-0174314

US3032343
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:56:17
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'YEARS'	System	01 Sep 2020 22:17:32

FDA-CBER-2022-1614-0174315

US3032343
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:56:17
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '29'	System	01 Sep 2020 16:27:18

FDA-CBER-2022-1614-0174316

US3032343
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:56:17
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Female (F)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:17:32

FDA-CBER-2022-1614-0174317

US3032343
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:56:17
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:17:32

US3032343
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:56:17
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '1'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:17:32

FDA-CBER-2022-1614-0174319

US3032343
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:56:17
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:17:32

FDA-CBER-2022-1614-0174320

US3032343
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:56:17
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:17:32

FDA-CBER-2022-1614-0174321

US3032343
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:56:17
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:17:32

FDA-CBER-2022-1614-0174322

US3032343
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:56:17
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:17:32

FDA-CBER-2022-1614-0174323

US3032343
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:56:17
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:17:32

FDA-CBER-2022-1614-0174324

US3032343
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:56:17
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:17:32

FDA-CBER-2022-1614-0174325

US3032343
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:56:17
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:17:32

FDA-CBER-2022-1614-0174326

US3032343
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:56:17
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:17:32

FDA-CBER-2022-1614-0174327

US3032343
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:56:17
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '1 Sep 2020'	Kelsey Kelley (b) (4) (b) (4)	01 Sep 2020 16:27:18

FDA-CBER-2022-1614-0174328

US3032343
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:56:17
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'Sep 2020'	System	01 Sep 2020 16:27:18

FDA-CBER-2022-1614-0174329

US3032343
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:56:17
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '2020'	System	01 Sep 2020 16:27:18

FDA-CBER-2022-1614-0174330

US3032343
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:56:17
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Amendment 3 (3)'	Kelsey Kelley (b) (4) (b) (4)	01 Sep 2020 16:27:18

FDA-CBER-2022-1614-0174331

US3032343
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:56:17
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	01 Sep 2020 16:27:18

FDA-CBER-2022-1614-0174332

US3032343
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:56:17
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	01 Sep 2020 16:27:18

US3032343
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:56:17
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	01 Sep 2020 16:27:18

FDA-CBER-2022-1614-0174334

US3032343
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:56:17
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	01 Sep 2020 16:27:18

FDA-CBER-2022-1614-0174335

US3032343
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:56:17
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:34:55

FDA-CBER-2022-1614-0174336

US3032343
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:56:17
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '1'	System	01 Sep 2020 16:27:21

FDA-CBER-2022-1614-0174337

US3032343
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 11 Aug 2021 21:56:17
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	01 Sep 2020 16:27:21

FDA-CBER-2022-1614-0174338

US3032343
Folder: Screening
Form: Medical History Summary
Generated On: 11 Aug 2021 21:56:17
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User closed query 'Per CDM: It appears participant is 29 years of age, yet there are no Medical History or Concomitant Medications recorded. Please review, reconcile, and update ALL applicable forms accordingly.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 11:59:13
Query 'Per CDM: It appears participant is 29 years of age, yet there are no Medical History or Concomitant Medications recorded. Please review, reconcile, and update ALL applicable forms accordingly.' answered with 'no MH per patient' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	16 Oct 2020 16:25:17
User opened query 'Per CDM: It appears participant is 29 years of age, yet there are no Medical History or Concomitant Medications recorded. Please review, reconcile, and update ALL applicable forms accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 15:56:29
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:17:41

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:18:44

FDA-CBER-2022-1614-0174340

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '01 Sep 2020'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:18:44

FDA-CBER-2022-1614-0174341

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '09:25'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:18:44

FDA-CBER-2022-1614-0174342

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '01 Sep 2020 09:25'	System	01 Sep 2020 22:18:44

FDA-CBER-2022-1614-0174343

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '160.0' cm	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:18:44
DataPoint set to visible.	System	01 Sep 2020 16:27:21

FDA-CBER-2022-1614-0174344

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '68.4' kg	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:18:44
DataPoint set to visible.	System	01 Sep 2020 16:27:21

FDA-CBER-2022-1614-0174345

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '26.71875'	System	01 Sep 2020 22:18:44
DataPoint set to visible.	System	01 Sep 2020 16:27:21

FDA-CBER-2022-1614-0174346

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'kg/m2'	System	01 Sep 2020 22:18:44
DataPoint set to visible.	System	01 Sep 2020 16:27:21

FDA-CBER-2022-1614-0174347

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:57:02
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 05:14:44
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 16:01:12
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 16:01:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 16:01:07
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:42:27
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '36.6' C	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:18:44

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:57:02
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 16:01:07
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 16:01:07
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Oral (Oral)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:18:44

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:18:44

FDA-CBER-2022-1614-0174350

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:57:02
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 16:01:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 16:01:07
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '83'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:18:44

FDA-CBER-2022-1614-0174351

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'bpm'	System	01 Sep 2020 22:18:44

FDA-CBER-2022-1614-0174352

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:57:02
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 16:01:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 16:01:07
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '16'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:18:44

FDA-CBER-2022-1614-0174353

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'breaths/min'	System	01 Sep 2020 22:18:44

FDA-CBER-2022-1614-0174354

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:57:02
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 16:01:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 16:01:07
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '106'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:18:44

FDA-CBER-2022-1614-0174355

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'mmHg'	System	01 Sep 2020 22:18:44

FDA-CBER-2022-1614-0174356

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:57:02
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 16:01:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 16:01:07
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '74'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:18:44

FDA-CBER-2022-1614-0174357

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'mmHg'	System	01 Sep 2020 22:18:44

FDA-CBER-2022-1614-0174358

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25

FDA-CBER-2022-1614-0174359

US3032343
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25

FDA-CBER-2022-1614-0174360

US3032343
Folder: Screening
Form: Physical Examination
Generated On: 11 Aug 2021 21:56:17
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:18:53

FDA-CBER-2022-1614-0174361

US3032343
Folder: Screening
Form: Physical Examination
Generated On: 11 Aug 2021 21:56:17
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '01 Sep 2020'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:18:53

FDA-CBER-2022-1614-0174362

US3032343
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 21:56:17
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '01 Sep 2020'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:19:18

FDA-CBER-2022-1614-0174363

US3032343
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 21:56:17
Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:19:18

FDA-CBER-2022-1614-0174364

US3032343
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 21:56:17
If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:19:18

FDA-CBER-2022-1614-0174365

US3032343
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 21:56:17
If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:19:18

FDA-CBER-2022-1614-0174366

US3032343
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 21:56:17
If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:19:18

FDA-CBER-2022-1614-0174367

US3032343
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 21:56:17
Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:19:18

FDA-CBER-2022-1614-0174368

US3032343
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 21:56:17
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:19:18

FDA-CBER-2022-1614-0174369

US3032343
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 21:56:17
Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:19:18

FDA-CBER-2022-1614-0174370

US3032343
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:19:45

FDA-CBER-2022-1614-0174371

US3032343
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '01 Sep 2020'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:19:45

FDA-CBER-2022-1614-0174372

US3032343
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Urine (URINE)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:19:45

US3032343
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Negative (NEGATIVE)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:19:45

FDA-CBER-2022-1614-0174374

US3032343
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:19:45

US3032343
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User closed query 'Per CDM :Please note the FSH sample collected is answered as "NO" but the collection date and time has been provided.Kindly update appropriately' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 03:22:58
Query 'Per CDM :Please note the FSH sample collected is answered as "NO" but the collection date and time has been provided.Kindly update appropriately' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	23 Sep 2020 13:29:45
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	23 Sep 2020 13:29:36
User opened query 'Per CDM :Please note the FSH sample collected is answered as "NO" but the collection date and time has been provided.Kindly update appropriately' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 11:22:18
User entered '01 Sep 2020'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:19:45

US3032343
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	23 Sep 2020 13:29:36
User entered '09:15'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:19:45

FDA-CBER-2022-1614-0174377

US3032343
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	23 Sep 2020 13:29:36
User entered '01 Sep 2020 09:15'	System	01 Sep 2020 22:19:45

FDA-CBER-2022-1614-0174378

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

FDA-CBER-2022-1614-0174379

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

FDA-CBER-2022-1614-0174380

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17
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)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

FDA-CBER-2022-1614-0174381

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17
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)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

FDA-CBER-2022-1614-0174382

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

FDA-CBER-2022-1614-0174383

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17
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 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17
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 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

FDA-CBER-2022-1614-0174385

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17
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 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17
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)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

FDA-CBER-2022-1614-0174387

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17
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)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

FDA-CBER-2022-1614-0174388

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17
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)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

FDA-CBER-2022-1614-0174389

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

FDA-CBER-2022-1614-0174390

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

FDA-CBER-2022-1614-0174391

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '1'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

FDA-CBER-2022-1614-0174392

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

FDA-CBER-2022-1614-0174393

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17

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)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

FDA-CBER-2022-1614-0174394

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17
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)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

FDA-CBER-2022-1614-0174395

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17

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 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

FDA-CBER-2022-1614-0174396

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

FDA-CBER-2022-1614-0174397

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

FDA-CBER-2022-1614-0174398

US3032343
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:56:17
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:23

FDA-CBER-2022-1614-0174399

US3032343
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:40

FDA-CBER-2022-1614-0174400

US3032343
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '01 Sep 2020'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:40

FDA-CBER-2022-1614-0174401

US3032343
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Clinic (Clinic)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:20:40

FDA-CBER-2022-1614-0174402

US3032343
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered 'VISIT1'	System	01 Sep 2020 22:20:40

FDA-CBER-2022-1614-0174403

US3032343
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 21:56:17
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:44:33

FDA-CBER-2022-1614-0174404

US3032343
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 21:56:17
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '108996'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:44:33

FDA-CBER-2022-1614-0174405

US3032343
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 21:56:17
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:44:33

FDA-CBER-2022-1614-0174406

US3032343

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:56:17

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:21:24

US3032343
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 21:56:17

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:21:24

FDA-CBER-2022-1614-0174408

US3032343
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 21:56:17
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:21:24

FDA-CBER-2022-1614-0174409

US3032343
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 21:56:17
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:21:24

FDA-CBER-2022-1614-0174410

US3032343
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 21:56:17
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:21:24

FDA-CBER-2022-1614-0174411

US3032343
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 21:56:17
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4)	02 Nov 2020 22:28:15
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 09:04:27
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	29 Oct 2020 21:23:34
User entered 'No (N)'	Linden DeBoer (b) (4)	29 Oct 2020 21:23:19
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 12:46:19
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:54:28
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:54:27

FDA-CBER-2022-1614-0174412

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:56:17
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	14 Oct 2020 19:48:36
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 06:26:59
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:37:26
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:37:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:37:20
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:59:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '160.0' cm	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174413

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:56:17
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	14 Oct 2020 19:48:36
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:37:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:37:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '68.4' kg	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174414

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:56:17
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	14 Oct 2020 19:48:36
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 06:26:59
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:37:26
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:37:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:37:20
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:59:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '160.0' cm	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174415

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:56:17
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	14 Oct 2020 19:48:36
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:37:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:37:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '68.4' kg	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174416

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User accepted default value 'Pre-Dose (PREDOSE)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174417

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174418

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '01 Sep 2020'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174419

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '09:25'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174420

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered '01 Sep 2020 09:25'	System	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174421

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '36.6' C	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174422

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Oral (Oral)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174423

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174424

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '83'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174425

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered 'bpm'	System	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174426

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '16'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174427

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered 'breaths/min'	System	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174428

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '106'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174429

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered 'mmHg'	System	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174430

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '74'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174431

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered 'mmHg'	System	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174432

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:56:17
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	14 Oct 2020 19:48:36
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 06:26:59
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:37:26
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:37:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:37:20
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:59:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '160.0' cm	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174433

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:56:17
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	14 Oct 2020 19:48:36
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:37:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:37:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '68.4' kg	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174434

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User accepted default value 'Post-Dose (POSTDOSE)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174435

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174436

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '01 Sep 2020'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174437

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '11:58'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174438

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered '01 Sep 2020 11:58'	System	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174439

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '36.6' C	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174440

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Oral (Oral)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174441

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174442

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '64'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174443

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered 'bpm'	System	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174444

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '14'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174445

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered 'breaths/min'	System	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174446

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '121'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174447

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered 'mmHg'	System	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174448

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '87'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174449

US3032343
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered 'mmHg'	System	01 Sep 2020 22:22:47

FDA-CBER-2022-1614-0174450

US3032343
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 11 Aug 2021 21:56:17
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:23:02

FDA-CBER-2022-1614-0174451

US3032343
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 11 Aug 2021 21:56:17
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '01 Sep 2020'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:23:02

FDA-CBER-2022-1614-0174452

US3032343
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User closed query 'Per CDM , please note as the screening and Visit 1 is on the same day the Pregnancy test performed in visit 1 should be "NO" . kindly update ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 05:29:23
Query 'Per CDM , please note as the screening and Visit 1 is on the same day the Pregnancy test performed in visit 1 should be "NO" . kindly update ' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	25 Sep 2020 13:19:13
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	25 Sep 2020 13:19:06
User opened query 'Per CDM , please note as the screening and Visit 1 is on the same day the Pregnancy test performed in visit 1 should be "NO" . kindly update ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 03:40:55
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:23:20

FDA-CBER-2022-1614-0174453

US3032343
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	25 Sep 2020 13:19:06
User entered '01 Sep 2020'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:23:20

FDA-CBER-2022-1614-0174454

US3032343
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	25 Sep 2020 13:19:06
User entered 'Urine (URINE)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:23:20

US3032343
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	25 Sep 2020 13:19:06
User entered 'Negative (NEGATIVE)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:23:20

US3032343
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:23:20

FDA-CBER-2022-1614-0174457

US3032343
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User closed query 'Per CDM :Please note the FSH sample collected is answered as "NO" but the collection date and time has been provided. Kindly remove the date and time if sample was not collected.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 03:39:54
Query 'Per CDM :Please note the FSH sample collected is answered as "NO" but the collection date and time has been provided. Kindly remove the date and time if sample was not collected.' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	23 Sep 2020 13:32:09
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	23 Sep 2020 13:31:48
User opened query 'Per CDM :Please note the FSH sample collected is answered as "NO" but the collection date and time has been provided. Kindly remove the date and time if sample was not collected.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:10:43
User entered '01 Sep 2020'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:23:20

FDA-CBER-2022-1614-0174458

US3032343
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	23 Sep 2020 13:31:48
User entered '09:15'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:23:20

FDA-CBER-2022-1614-0174459

US3032343
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered empty.	System	23 Sep 2020 13:31:48
User entered '01 Sep 2020 09:15'	System	01 Sep 2020 22:23:20

FDA-CBER-2022-1614-0174460

US3032343
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:56:17
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174461

US3032343
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:56:17
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174462

US3032343

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:56:17

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	01 Sep 2020 16:28:03

US3032343
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:56:17
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174464

US3032343
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:56:17
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '1 Sep 2020'	Kelsey Kelley (b) (4) (b) (4)	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174465

US3032343
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:56:17
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '11:21'	Kelsey Kelley (b) (4) (b) (4)	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174466

US3032343
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:56:17
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered '1 Sep 2020 11:21'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174467

US3032343
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:56:17
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Left Arm (LEFT ARM)'	Kelsey Kelley (b) (4) (b) (4)	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174468

US3032343
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:56:17
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered 'ONCE'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174469

US3032343
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:56:17
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174470

US3032343
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:56:17
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:23:52

US3032343
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:56:17
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '01 Sep 2020'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:23:52

FDA-CBER-2022-1614-0174472

US3032343
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:56:17
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '10:34'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:23:52

FDA-CBER-2022-1614-0174473

US3032343
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:56:17
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered '01 Sep 2020 10:34'	System	01 Sep 2020 22:23:52

FDA-CBER-2022-1614-0174474

US3032343
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 11 Aug 2021 21:56:17
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '01 Sep 2020'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:24:07

FDA-CBER-2022-1614-0174475

US3032343
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 21:56:17
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:24:07

FDA-CBER-2022-1614-0174476

US3032343
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 21:56:17
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:24:07

US3032343
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 21:56:17
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '09:45'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:24:07

FDA-CBER-2022-1614-0174478

US3032343
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 21:56:17
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered '01 Sep 2020 09:45'	System	01 Sep 2020 22:24:07

US3032343
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 21:56:17
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:24:07

FDA-CBER-2022-1614-0174480

US3032343
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 21:56:17
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:50:50
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	30 Nov 2020 22:55:30
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	30 Nov 2020 22:55:30
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:24:07

FDA-CBER-2022-1614-0174481

US3032343
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 21:56:17
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:50:50
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	30 Nov 2020 22:55:30
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	30 Nov 2020 22:55:30
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '09:45'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:24:07

FDA-CBER-2022-1614-0174482

US3032343
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 21:56:17
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered empty.	System	30 Nov 2020 22:55:30
User entered '01 Sep 2020 09:45'	System	01 Sep 2020 22:24:07

FDA-CBER-2022-1614-0174483

US3032343
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	01 Sep 2020 22:24:11

FDA-CBER-2022-1614-0174484

US3032343
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered '1'	System	01 Sep 2020 22:24:11

FDA-CBER-2022-1614-0174485

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174486

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T11:55:52', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e6156a5b-2389-4030-8abe-76fa2b530d27'	System	01 Sep 2020 16:57:30
User entered 'Yes (Y)'	System	01 Sep 2020 16:57:30

FDA-CBER-2022-1614-0174487

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T11:57:13', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e6156a5b-2389-4030-8abe-76fa2b530d27'	System	01 Sep 2020 16:57:30
User entered '97.3'	System	01 Sep 2020 16:57:30

FDA-CBER-2022-1614-0174488

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T11:57:20', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e6156a5b-2389-4030-8abe-76fa2b530d27'	System	01 Sep 2020 16:57:30
User entered 'No (N)'	System	01 Sep 2020 16:57:30

FDA-CBER-2022-1614-0174489

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T11:57:26', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e6156a5b-2389-4030-8abe-76fa2b530d27'	System	01 Sep 2020 16:57:30
User entered '01 Sep 2020 11:57'	System	01 Sep 2020 16:57:30

FDA-CBER-2022-1614-0174490

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '01 Sep 2020 11:41'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174491

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '01 Sep 2020 14:11'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174492

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174493

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T15:55:58', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '7c377a53-8b7a-46b3-a969-48b943ccd364'	System	01 Sep 2020 20:56:22
User entered 'Yes (Y)'	System	01 Sep 2020 20:56:22

FDA-CBER-2022-1614-0174494

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T15:56:10', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '7c377a53-8b7a-46b3-a969-48b943ccd364'	System	01 Sep 2020 20:56:22
User entered '98.7'	System	01 Sep 2020 20:56:22

FDA-CBER-2022-1614-0174495

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T15:56:14', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '7c377a53-8b7a-46b3-a969-48b943ccd364'	System	01 Sep 2020 20:56:22
User entered 'No (N)'	System	01 Sep 2020 20:56:22

FDA-CBER-2022-1614-0174496

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T15:56:17', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '7c377a53-8b7a-46b3-a969-48b943ccd364'	System	01 Sep 2020 20:56:22
User entered '01 Sep 2020 15:56'	System	01 Sep 2020 20:56:22

FDA-CBER-2022-1614-0174497

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '01 Sep 2020 15:06'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174498

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174499

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 2'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174500

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:56:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-02T12:10:47', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '7b8666d7-75db-4f87-8187-f6821d20d805'	System	02 Sep 2020 17:11:24
User entered 'Yes (Y)'	System	02 Sep 2020 17:11:24

FDA-CBER-2022-1614-0174501

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:56:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-02T12:10:53', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '7b8666d7-75db-4f87-8187-f6821d20d805'	System	02 Sep 2020 17:11:24
User entered '98.9'	System	02 Sep 2020 17:11:24

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:56:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-02T12:11:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '7b8666d7-75db-4f87-8187-f6821d20d805'	System	02 Sep 2020 17:11:24
User entered 'Yes (Y)'	System	02 Sep 2020 17:11:24

FDA-CBER-2022-1614-0174503

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:56:17
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-02T12:11:15', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '7b8666d7-75db-4f87-8187-f6821d20d805'	System	02 Sep 2020 17:11:24
User entered '0'	System	02 Sep 2020 17:11:24

FDA-CBER-2022-1614-0174504

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:56:17
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User closed query 'Per the participant response, medication was taken to prevent 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).		15 Sep 2020 10:35:51
Query 'Per the participant response, medication was taken to prevent 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 'data entered' (Site from System).		14 Sep 2020 21:26:04
User opened query 'Per the participant response, medication was taken to prevent 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 Sep 2020 17:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-02T12:11:15', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '7b8666d7-75db-4f87-8187-f6821d20d805'	System	02 Sep 2020 17:11:24
User entered '1'	System	02 Sep 2020 17:11:24

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-02T12:11:20', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '7b8666d7-75db-4f87-8187-f6821d20d805'	System	02 Sep 2020 17:11:24
User entered '02 Sep 2020 12:11'	System	02 Sep 2020 17:11:24

FDA-CBER-2022-1614-0174506

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174507

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174508

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 3'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174509

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:56:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-03T12:00:16', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'd2fefc90-e310-4ea2-a9d8-84440456291d'	System	03 Sep 2020 17:00:37
User entered 'Yes (Y)'	System	03 Sep 2020 17:00:37

FDA-CBER-2022-1614-0174510

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:56:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-03T12:00:22', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'd2fefc90-e310-4ea2-a9d8-84440456291d'	System	03 Sep 2020 17:00:37
User entered '98.9'	System	03 Sep 2020 17:00:37

FDA-CBER-2022-1614-0174511

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:56:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-03T12:00:25', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'd2fefc90-e310-4ea2-a9d8-84440456291d'	System	03 Sep 2020 17:00:37
User entered 'No (N)'	System	03 Sep 2020 17:00:37

FDA-CBER-2022-1614-0174512

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-03T12:00:29', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'd2fefc90-e310-4ea2-a9d8-84440456291d'	System	03 Sep 2020 17:00:37
User entered '03 Sep 2020 12:00'	System	03 Sep 2020 17:00:37

FDA-CBER-2022-1614-0174513

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174514

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174515

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 4'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174516

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:56:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-04T12:00:22', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'aa366113-00ef-4dd8-92fe-7eb3fa8d4b08'	System	04 Sep 2020 17:01:18
User entered 'Yes (Y)'	System	04 Sep 2020 17:01:18

FDA-CBER-2022-1614-0174517

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:56:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-04T12:00:27', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'aa366113-00ef-4dd8-92fe-7eb3fa8d4b08'	System	04 Sep 2020 17:01:18
User entered '98.9'	System	04 Sep 2020 17:01:18

FDA-CBER-2022-1614-0174518

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:56:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-04T12:00:32', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'aa366113-00ef-4dd8-92fe-7eb3fa8d4b08'	System	04 Sep 2020 17:01:18
User entered 'No (N)'	System	04 Sep 2020 17:01:18

FDA-CBER-2022-1614-0174519

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-04T12:00:49', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'aa366113-00ef-4dd8-92fe-7eb3fa8d4b08'	System	04 Sep 2020 17:01:18
User entered '04 Sep 2020 12:00'	System	04 Sep 2020 17:01:18

FDA-CBER-2022-1614-0174520

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174521

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174522

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 5'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174523

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:56:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-05T12:49:21', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e32b78f5-85fa-4fff-907c-5dd56231770a'	System	05 Sep 2020 17:49:36
User entered 'Yes (Y)'	System	05 Sep 2020 17:49:36

FDA-CBER-2022-1614-0174524

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:56:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-05T12:49:27', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e32b78f5-85fa-4fff-907c-5dd56231770a'	System	05 Sep 2020 17:49:36
User entered '99.1'	System	05 Sep 2020 17:49:36

FDA-CBER-2022-1614-0174525

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:56:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD)', Time: '2020-09-05T12:49:31', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e32b78f5-85fa-4fff-907c-5dd56231770a'	System	05 Sep 2020 17:49:36
User entered 'No (N)'	System	05 Sep 2020 17:49:36

FDA-CBER-2022-1614-0174526

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-05T12:49:33', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e32b78f5-85fa-4fff-907c-5dd56231770a'	System	05 Sep 2020 17:49:36
User entered '05 Sep 2020 12:49'	System	05 Sep 2020 17:49:36

FDA-CBER-2022-1614-0174527

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174528

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174529

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 6'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174530

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:56:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-06T12:00:20', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '7284ca0a-833d-4ef1-9945-7d7aee638b4b'	System	06 Sep 2020 17:00:38
User entered 'Yes (Y)'	System	06 Sep 2020 17:00:38

FDA-CBER-2022-1614-0174531

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:56:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-06T12:00:25', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '7284ca0a-833d-4ef1-9945-7d7aee638b4b'	System	06 Sep 2020 17:00:38
User entered '98.9'	System	06 Sep 2020 17:00:38

FDA-CBER-2022-1614-0174532

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:56:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-06T12:00:28', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '7284ca0a-833d-4ef1-9945-7d7aee638b4b'	System	06 Sep 2020 17:00:38
User entered 'No (N)'	System	06 Sep 2020 17:00:38

FDA-CBER-2022-1614-0174533

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-06T12:00:30', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '7284ca0a-833d-4ef1-9945-7d7aee638b4b'	System	06 Sep 2020 17:00:38
User entered '06 Sep 2020 12:00'	System	06 Sep 2020 17:00:38

FDA-CBER-2022-1614-0174534

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174535

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174536

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 7'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174537

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:56:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-07T13:05:10', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '2e719391-40a0-478a-b200-2ee8a8c96a5e'	System	07 Sep 2020 18:05:30
User entered 'Yes (Y)'	System	07 Sep 2020 18:05:30

FDA-CBER-2022-1614-0174538

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:56:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-07T13:05:18', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '2e719391-40a0-478a-b200-2ee8a8c96a5e'	System	07 Sep 2020 18:05:30
User entered '98.9'	System	07 Sep 2020 18:05:30

FDA-CBER-2022-1614-0174539

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:56:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-07T13:05:25', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '2e719391-40a0-478a-b200-2ee8a8c96a5e'	System	07 Sep 2020 18:05:30
User entered 'No (N)'	System	07 Sep 2020 18:05:30

FDA-CBER-2022-1614-0174540

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-07T13:05:27', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '2e719391-40a0-478a-b200-2ee8a8c96a5e'	System	07 Sep 2020 18:05:30
User entered '07 Sep 2020 13:05'	System	07 Sep 2020 18:05:30

FDA-CBER-2022-1614-0174541

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174542

US3032343
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174543

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174544

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T11:58:02', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '8e6c712f-e9b2-4a1b-b8d1-5dff511fa2fd'	System	01 Sep 2020 16:58:18
User entered 'None (1)'	System	01 Sep 2020 16:58:18

FDA-CBER-2022-1614-0174545

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T11:58:06', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '8e6c712f-e9b2-4a1b-b8d1-5dff511fa2fd'	System	01 Sep 2020 16:58:18
User entered 'No (N)'	System	01 Sep 2020 16:58:18

FDA-CBER-2022-1614-0174546

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T11:58:08', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '8e6c712f-e9b2-4a1b-b8d1-5dff511fa2fd'	System	01 Sep 2020 16:58:18
User entered 'No (N)'	System	01 Sep 2020 16:58:18

FDA-CBER-2022-1614-0174547

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T11:58:12', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '8e6c712f-e9b2-4a1b-b8d1-5dff511fa2fd'	System	01 Sep 2020 16:58:18
User entered 'None (1)'	System	01 Sep 2020 16:58:18

FDA-CBER-2022-1614-0174548

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T11:58:15', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '8e6c712f-e9b2-4a1b-b8d1-5dff511fa2fd'	System	01 Sep 2020 16:58:18
User entered '01 Sep 2020 11:58'	System	01 Sep 2020 16:58:18

FDA-CBER-2022-1614-0174549

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '01 Sep 2020 11:41'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174550

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '01 Sep 2020 14:11'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174551

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174552

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T15:56:27', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bba1333e-bd70-4d38-ade1-432b13f1468c'	System	01 Sep 2020 20:56:53
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 20:56:53

FDA-CBER-2022-1614-0174553

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T15:56:40', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bba1333e-bd70-4d38-ade1-432b13f1468c'	System	01 Sep 2020 20:56:53
User entered 'No (N)'	System	01 Sep 2020 20:56:53

FDA-CBER-2022-1614-0174554

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T15:56:43', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bba1333e-bd70-4d38-ade1-432b13f1468c'	System	01 Sep 2020 20:56:53
User entered 'No (N)'	System	01 Sep 2020 20:56:53

FDA-CBER-2022-1614-0174555

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T15:56:48', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bba1333e-bd70-4d38-ade1-432b13f1468c'	System	01 Sep 2020 20:56:53
User entered 'None (1)'	System	01 Sep 2020 20:56:53

FDA-CBER-2022-1614-0174556

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T15:56:50', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bba1333e-bd70-4d38-ade1-432b13f1468c'	System	01 Sep 2020 20:56:53
User entered '01 Sep 2020 15:56'	System	01 Sep 2020 20:56:53

FDA-CBER-2022-1614-0174557

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '01 Sep 2020 15:06'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174558

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174559

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 2'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174560

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:56:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-02T12:11:42', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'ef0d3f45-329c-4a39-8bb1-e927610e522d'	System	02 Sep 2020 17:12:42
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	02 Sep 2020 17:12:42

FDA-CBER-2022-1614-0174561

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:56:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-02T12:12:09', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'ef0d3f45-329c-4a39-8bb1-e927610e522d'	System	02 Sep 2020 17:12:42
User entered 'No (N)'	System	02 Sep 2020 17:12:42

FDA-CBER-2022-1614-0174562

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:56:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-02T12:12:28', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'ef0d3f45-329c-4a39-8bb1-e927610e522d'	System	02 Sep 2020 17:12:42
User entered 'No (N)'	System	02 Sep 2020 17:12:42

FDA-CBER-2022-1614-0174563

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:56:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-02T12:12:36', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'ef0d3f45-329c-4a39-8bb1-e927610e522d'	System	02 Sep 2020 17:12:42
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	02 Sep 2020 17:12:42

FDA-CBER-2022-1614-0174564

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-02T12:12:40', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'ef0d3f45-329c-4a39-8bb1-e927610e522d'	System	02 Sep 2020 17:12:42
User entered '02 Sep 2020 12:12'	System	02 Sep 2020 17:12:42

FDA-CBER-2022-1614-0174565

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174566

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174567

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 3'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174568

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:56:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-03T12:00:43', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '144f675b-495f-40c3-8ee9-7919deec2691'	System	03 Sep 2020 17:01:12
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 17:01:12

FDA-CBER-2022-1614-0174569

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:56:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-03T12:00:47', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '144f675b-495f-40c3-8ee9-7919deec2691'	System	03 Sep 2020 17:01:12
User entered 'No (N)'	System	03 Sep 2020 17:01:12

FDA-CBER-2022-1614-0174570

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:56:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-03T12:00:53', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '144f675b-495f-40c3-8ee9-7919deec2691'	System	03 Sep 2020 17:01:12
User entered 'No (N)'	System	03 Sep 2020 17:01:12

FDA-CBER-2022-1614-0174571

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:56:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-03T12:00:57', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '144f675b-495f-40c3-8ee9-7919deec2691'	System	03 Sep 2020 17:01:12
User entered 'None (1)'	System	03 Sep 2020 17:01:12

FDA-CBER-2022-1614-0174572

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-03T12:01:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '144f675b-495f-40c3-8ee9-7919deec2691'	System	03 Sep 2020 17:01:12
User entered '03 Sep 2020 12:01'	System	03 Sep 2020 17:01:12

FDA-CBER-2022-1614-0174573

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174574

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174575

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 4'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174576

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:56:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-04T12:00:56', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'da7dcbaf-d368-4115-a904-aa5f1624de17'	System	04 Sep 2020 17:01:55
User entered 'None (1)'	System	04 Sep 2020 17:01:55

FDA-CBER-2022-1614-0174577

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:56:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-04T12:00:59', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'da7dcbaf-d368-4115-a904-aa5f1624de17'	System	04 Sep 2020 17:01:55
User entered 'No (N)'	System	04 Sep 2020 17:01:55

FDA-CBER-2022-1614-0174578

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:56:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-04T12:01:11', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'da7dcbaf-d368-4115-a904-aa5f1624de17'	System	04 Sep 2020 17:01:55
User entered 'No (N)'	System	04 Sep 2020 17:01:55

FDA-CBER-2022-1614-0174579

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:56:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-04T12:01:13', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'da7dcbaf-d368-4115-a904-aa5f1624de17'	System	04 Sep 2020 17:01:55
User entered 'None (1)'	System	04 Sep 2020 17:01:55

FDA-CBER-2022-1614-0174580

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-04T12:01:15', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'da7dcbaf-d368-4115-a904-aa5f1624de17'	System	04 Sep 2020 17:01:55
User entered '04 Sep 2020 12:01'	System	04 Sep 2020 17:01:55

FDA-CBER-2022-1614-0174581

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174582

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174583

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 5'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174584

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:56:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-05T12:49:38', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'c9b8fc76-e12f-4ce7-9d60-319f7fc18cc8'	System	05 Sep 2020 17:49:52
User entered 'None (1)'	System	05 Sep 2020 17:49:52

FDA-CBER-2022-1614-0174585

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:56:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-05T12:49:41', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'c9b8fc76-e12f-4ce7-9d60-319f7fc18cc8'	System	05 Sep 2020 17:49:52
User entered 'No (N)'	System	05 Sep 2020 17:49:52

FDA-CBER-2022-1614-0174586

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:56:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-05T12:49:43', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'c9b8fc76-e12f-4ce7-9d60-319f7fc18cc8'	System	05 Sep 2020 17:49:52
User entered 'No (N)'	System	05 Sep 2020 17:49:52

FDA-CBER-2022-1614-0174587

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:56:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-05T12:49:46', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'c9b8fc76-e12f-4ce7-9d60-319f7fc18cc8'	System	05 Sep 2020 17:49:52
User entered 'None (1)'	System	05 Sep 2020 17:49:52

FDA-CBER-2022-1614-0174588

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-05T12:49:50', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'c9b8fc76-e12f-4ce7-9d60-319f7fc18cc8'	System	05 Sep 2020 17:49:52
User entered '05 Sep 2020 12:49'	System	05 Sep 2020 17:49:52

FDA-CBER-2022-1614-0174589

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174590

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174591

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 6'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174592

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:56:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-06T12:00:35', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'beea02df-5a21-4555-bff9-f480798190e7'	System	06 Sep 2020 17:00:56
User entered 'None (1)'	System	06 Sep 2020 17:00:56

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:56:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-06T12:00:38', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'beea02df-5a21-4555-bff9-f480798190e7'	System	06 Sep 2020 17:00:56
User entered 'No (N)'	System	06 Sep 2020 17:00:56

FDA-CBER-2022-1614-0174594

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:56:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD)', Time: '2020-09-06T12:00:41', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'beea02df-5a21-4555-bff9-f480798190e7'	System	06 Sep 2020 17:00:56
User entered 'No (N)'	System	06 Sep 2020 17:00:56

FDA-CBER-2022-1614-0174595

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:56:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-06T12:00:43', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'beea02df-5a21-4555-bff9-f480798190e7'	System	06 Sep 2020 17:00:56
User entered 'None (1)'	System	06 Sep 2020 17:00:56

FDA-CBER-2022-1614-0174596

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-06T12:00:46', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'beea02df-5a21-4555-bff9-f480798190e7'	System	06 Sep 2020 17:00:56
User entered '06 Sep 2020 12:00'	System	06 Sep 2020 17:00:56

FDA-CBER-2022-1614-0174597

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174598

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174599

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 7'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174600

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:56:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-07T13:05:30', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '71949741-f203-4bc3-88e8-d81e4dc840ce'	System	07 Sep 2020 18:05:42
User entered 'None (1)'	System	07 Sep 2020 18:05:42

FDA-CBER-2022-1614-0174601

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:56:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-07T13:05:33', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '71949741-f203-4bc3-88e8-d81e4dc840ce'	System	07 Sep 2020 18:05:42
User entered 'No (N)'	System	07 Sep 2020 18:05:42

FDA-CBER-2022-1614-0174602

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:56:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-07T13:05:35', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '71949741-f203-4bc3-88e8-d81e4dc840ce'	System	07 Sep 2020 18:05:42
User entered 'No (N)'	System	07 Sep 2020 18:05:42

FDA-CBER-2022-1614-0174603

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:56:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-07T13:05:36', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '71949741-f203-4bc3-88e8-d81e4dc840ce'	System	07 Sep 2020 18:05:42
User entered 'None (1)'	System	07 Sep 2020 18:05:42

FDA-CBER-2022-1614-0174604

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-07T13:05:39', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '71949741-f203-4bc3-88e8-d81e4dc840ce'	System	07 Sep 2020 18:05:42
User entered '07 Sep 2020 13:05'	System	07 Sep 2020 18:05:42

FDA-CBER-2022-1614-0174605

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174606

US3032343
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174607

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174608

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T11:58:22', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f6a7a67a-7aa2-46fc-b74a-77a48707be4a'	System	01 Sep 2020 16:58:43
User entered 'None (0)'	System	01 Sep 2020 16:58:43

FDA-CBER-2022-1614-0174609

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T11:58:25', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f6a7a67a-7aa2-46fc-b74a-77a48707be4a'	System	01 Sep 2020 16:58:43
User entered 'None (0)'	System	01 Sep 2020 16:58:43

FDA-CBER-2022-1614-0174610

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T11:58:28', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f6a7a67a-7aa2-46fc-b74a-77a48707be4a'	System	01 Sep 2020 16:58:43
User entered 'None (0)'	System	01 Sep 2020 16:58:43

FDA-CBER-2022-1614-0174611

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T11:58:30', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f6a7a67a-7aa2-46fc-b74a-77a48707be4a'	System	01 Sep 2020 16:58:43
User entered 'None (0)'	System	01 Sep 2020 16:58:43

FDA-CBER-2022-1614-0174612

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T11:58:32', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f6a7a67a-7aa2-46fc-b74a-77a48707be4a'	System	01 Sep 2020 16:58:43
User entered 'None (0)'	System	01 Sep 2020 16:58:43

FDA-CBER-2022-1614-0174613

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T11:58:33', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f6a7a67a-7aa2-46fc-b74a-77a48707be4a'	System	01 Sep 2020 16:58:43
User entered 'None (0)'	System	01 Sep 2020 16:58:43

FDA-CBER-2022-1614-0174614

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD)', Time: '2020-09-01T11:58:36', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f6a7a67a-7aa2-46fc-b74a-77a48707be4a'	System	01 Sep 2020 16:58:43
User entered 'No (N)'	System	01 Sep 2020 16:58:43

FDA-CBER-2022-1614-0174615

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T11:58:38', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f6a7a67a-7aa2-46fc-b74a-77a48707be4a'	System	01 Sep 2020 16:58:43
User entered '01 Sep 2020 11:58'	System	01 Sep 2020 16:58:43

FDA-CBER-2022-1614-0174616

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '01 Sep 2020 11:41'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174617

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '01 Sep 2020 14:11'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174618

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174619

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T15:56:55', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bb9ff33a-70af-4a77-acdc-6422d3cc1d67'	System	01 Sep 2020 20:57:14
User entered 'None (0)'	System	01 Sep 2020 20:57:14

FDA-CBER-2022-1614-0174620

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD)', Time: '2020-09-01T15:56:59', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bb9ff33a-70af-4a77-acdc-6422d3cc1d67'	System	01 Sep 2020 20:57:14
User entered 'None (0)'	System	01 Sep 2020 20:57:14

FDA-CBER-2022-1614-0174621

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T15:57:01', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bb9ff33a-70af-4a77-acdc-6422d3cc1d67'	System	01 Sep 2020 20:57:14
User entered 'None (0)'	System	01 Sep 2020 20:57:14

FDA-CBER-2022-1614-0174622

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T15:57:03', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bb9ff33a-70af-4a77-acdc-6422d3cc1d67'	System	01 Sep 2020 20:57:14
User entered 'None (0)'	System	01 Sep 2020 20:57:14

FDA-CBER-2022-1614-0174623

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T15:57:05', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bb9ff33a-70af-4a77-acdc-6422d3cc1d67'	System	01 Sep 2020 20:57:14
User entered 'None (0)'	System	01 Sep 2020 20:57:14

FDA-CBER-2022-1614-0174624

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T15:57:07', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bb9ff33a-70af-4a77-acdc-6422d3cc1d67'	System	01 Sep 2020 20:57:14
User entered 'None (0)'	System	01 Sep 2020 20:57:14

FDA-CBER-2022-1614-0174625

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T15:57:09', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bb9ff33a-70af-4a77-acdc-6422d3cc1d67'	System	01 Sep 2020 20:57:14
User entered 'No (N)'	System	01 Sep 2020 20:57:14

FDA-CBER-2022-1614-0174626

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-01T15:57:11', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bb9ff33a-70af-4a77-acdc-6422d3cc1d67'	System	01 Sep 2020 20:57:14
User entered '01 Sep 2020 15:57'	System	01 Sep 2020 20:57:14

FDA-CBER-2022-1614-0174627

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '01 Sep 2020 15:06'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174628

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174629

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 2'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174630

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-02T12:12:46', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '763405bc-075d-4c26-ad25-eeba3700523d'	System	02 Sep 2020 17:13:36
User entered 'None (0)'	System	02 Sep 2020 17:13:36

FDA-CBER-2022-1614-0174631

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-02T12:12:50', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '763405bc-075d-4c26-ad25-eeba3700523d'	System	02 Sep 2020 17:13:36
User entered 'None (0)'	System	02 Sep 2020 17:13:36

FDA-CBER-2022-1614-0174632

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-02T12:12:59', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '763405bc-075d-4c26-ad25-eeba3700523d'	System	02 Sep 2020 17:13:36
User entered 'None (0)'	System	02 Sep 2020 17:13:36

FDA-CBER-2022-1614-0174633

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-02T12:13:02', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '763405bc-075d-4c26-ad25-eeba3700523d'	System	02 Sep 2020 17:13:36
User entered 'None (0)'	System	02 Sep 2020 17:13:36

FDA-CBER-2022-1614-0174634

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-02T12:13:07', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '763405bc-075d-4c26-ad25-eeba3700523d'	System	02 Sep 2020 17:13:36
User entered 'None (0)'	System	02 Sep 2020 17:13:36

FDA-CBER-2022-1614-0174635

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-02T12:13:25', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '763405bc-075d-4c26-ad25-eeba3700523d'	System	02 Sep 2020 17:13:36
User entered 'None (0)'	System	02 Sep 2020 17:13:36

FDA-CBER-2022-1614-0174636

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-02T12:13:28', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '763405bc-075d-4c26-ad25-eeba3700523d'	System	02 Sep 2020 17:13:36
User entered 'No (N)'	System	02 Sep 2020 17:13:36

FDA-CBER-2022-1614-0174637

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-02T12:13:31', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '763405bc-075d-4c26-ad25-eeba3700523d'	System	02 Sep 2020 17:13:36
User entered '02 Sep 2020 12:13'	System	02 Sep 2020 17:13:36

FDA-CBER-2022-1614-0174638

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174639

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174640

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 3'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174641

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-03T12:01:10', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b3cda73c-8c2b-47ff-ac72-8e7c0c950a30'	System	03 Sep 2020 17:02:00
User entered 'None (0)'	System	03 Sep 2020 17:02:00

FDA-CBER-2022-1614-0174642

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-03T12:01:13', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b3cda73c-8c2b-47ff-ac72-8e7c0c950a30'	System	03 Sep 2020 17:02:00
User entered 'None (0)'	System	03 Sep 2020 17:02:00

FDA-CBER-2022-1614-0174643

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-03T12:01:17', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b3cda73c-8c2b-47ff-ac72-8e7c0c950a30'	System	03 Sep 2020 17:02:00
User entered 'None (0)'	System	03 Sep 2020 17:02:00

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-03T12:01:22', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b3cda73c-8c2b-47ff-ac72-8e7c0c950a30'	System	03 Sep 2020 17:02:00
User entered 'None (0)'	System	03 Sep 2020 17:02:00

FDA-CBER-2022-1614-0174645

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-03T12:01:25', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b3cda73c-8c2b-47ff-ac72-8e7c0c950a30'	System	03 Sep 2020 17:02:00
User entered 'None (0)'	System	03 Sep 2020 17:02:00

FDA-CBER-2022-1614-0174646

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-03T12:01:28', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b3cda73c-8c2b-47ff-ac72-8e7c0c950a30'	System	03 Sep 2020 17:02:00
User entered 'None (0)'	System	03 Sep 2020 17:02:00

FDA-CBER-2022-1614-0174647

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-03T12:01:35', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b3cda73c-8c2b-47ff-ac72-8e7c0c950a30'	System	03 Sep 2020 17:02:00
User entered 'No (N)'	System	03 Sep 2020 17:02:00

FDA-CBER-2022-1614-0174648

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-03T12:01:39', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b3cda73c-8c2b-47ff-ac72-8e7c0c950a30'	System	03 Sep 2020 17:02:00
User entered '03 Sep 2020 12:01'	System	03 Sep 2020 17:02:00

FDA-CBER-2022-1614-0174649

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174650

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174651

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 4'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174652

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-04T12:01:26', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '5a1e168f-4ba7-4ed3-955a-f4c12065bbe4'	System	04 Sep 2020 17:02:54
User entered 'None (0)'	System	04 Sep 2020 17:02:54

FDA-CBER-2022-1614-0174653

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-04T12:01:32', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '5a1e168f-4ba7-4ed3-955a-f4c12065bbe4'	System	04 Sep 2020 17:02:54
User entered 'None (0)'	System	04 Sep 2020 17:02:54

FDA-CBER-2022-1614-0174654

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-04T12:01:33', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '5a1e168f-4ba7-4ed3-955a-f4c12065bbe4'	System	04 Sep 2020 17:02:54
User entered 'None (0)'	System	04 Sep 2020 17:02:54

FDA-CBER-2022-1614-0174655

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-04T12:01:34', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '5a1e168f-4ba7-4ed3-955a-f4c12065bbe4'	System	04 Sep 2020 17:02:54
User entered 'None (0)'	System	04 Sep 2020 17:02:54

FDA-CBER-2022-1614-0174656

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-04T12:01:48', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '5a1e168f-4ba7-4ed3-955a-f4c12065bbe4'	System	04 Sep 2020 17:02:54
User entered 'None (0)'	System	04 Sep 2020 17:02:54

FDA-CBER-2022-1614-0174657

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-04T12:01:50', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '5a1e168f-4ba7-4ed3-955a-f4c12065bbe4'	System	04 Sep 2020 17:02:54
User entered 'None (0)'	System	04 Sep 2020 17:02:54

FDA-CBER-2022-1614-0174658

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD)', Time: '2020-09-04T12:01:54', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '5a1e168f-4ba7-4ed3-955a-f4c12065bbe4'	System	04 Sep 2020 17:02:54
User entered 'No (N)'	System	04 Sep 2020 17:02:54

FDA-CBER-2022-1614-0174659

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-04T12:01:56', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '5a1e168f-4ba7-4ed3-955a-f4c12065bbe4'	System	04 Sep 2020 17:02:54
User entered '04 Sep 2020 12:01'	System	04 Sep 2020 17:02:54

FDA-CBER-2022-1614-0174660

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174661

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174662

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 5'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174663

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-05T12:50:02', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bfc50fcd-264e-4ef8-a622-ca7aeaceeea9'	System	05 Sep 2020 17:50:35
User entered 'None (0)'	System	05 Sep 2020 17:50:35

FDA-CBER-2022-1614-0174664

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-05T12:50:04', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bfc50fcd-264e-4ef8-a622-ca7aeaceeea9'	System	05 Sep 2020 17:50:35
User entered 'None (0)'	System	05 Sep 2020 17:50:35

FDA-CBER-2022-1614-0174665

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-05T12:50:07', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bfc50fcd-264e-4ef8-a622-ca7aeaceeea9'	System	05 Sep 2020 17:50:35
User entered 'None (0)'	System	05 Sep 2020 17:50:35

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-05T12:50:14', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bfc50fcd-264e-4ef8-a622-ca7aeaceeea9'	System	05 Sep 2020 17:50:35
User entered 'None (0)'	System	05 Sep 2020 17:50:35

FDA-CBER-2022-1614-0174667

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-05T12:50:16', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bfc50fcd-264e-4ef8-a622-ca7aeaceeea9'	System	05 Sep 2020 17:50:35
User entered 'None (0)'	System	05 Sep 2020 17:50:35

FDA-CBER-2022-1614-0174668

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-05T12:50:19', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bfc50fcd-264e-4ef8-a622-ca7aeaceeea9'	System	05 Sep 2020 17:50:35
User entered 'None (0)'	System	05 Sep 2020 17:50:35

FDA-CBER-2022-1614-0174669

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-05T12:50:25', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bfc50fcd-264e-4ef8-a622-ca7aeaceeea9'	System	05 Sep 2020 17:50:35
User entered 'No (N)'	System	05 Sep 2020 17:50:35

FDA-CBER-2022-1614-0174670

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-05T12:50:32', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bfc50fcd-264e-4ef8-a622-ca7aeaceeea9'	System	05 Sep 2020 17:50:35
User entered '05 Sep 2020 12:50'	System	05 Sep 2020 17:50:35

FDA-CBER-2022-1614-0174671

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174672

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174673

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 6'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174674

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-06T12:00:53', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b3973a84-7158-48e9-92a0-c1ffd7eb8dd7'	System	06 Sep 2020 17:01:34
User entered 'None (0)'	System	06 Sep 2020 17:01:34

FDA-CBER-2022-1614-0174675

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-06T12:00:55', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b3973a84-7158-48e9-92a0-c1ffd7eb8dd7'	System	06 Sep 2020 17:01:34
User entered 'None (0)'	System	06 Sep 2020 17:01:34

FDA-CBER-2022-1614-0174676

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-06T12:00:56', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b3973a84-7158-48e9-92a0-c1ffd7eb8dd7'	System	06 Sep 2020 17:01:34
User entered 'None (0)'	System	06 Sep 2020 17:01:34

FDA-CBER-2022-1614-0174677

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-06T12:00:58', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b3973a84-7158-48e9-92a0-c1ffd7eb8dd7'	System	06 Sep 2020 17:01:34
User entered 'None (0)'	System	06 Sep 2020 17:01:34

FDA-CBER-2022-1614-0174678

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-06T12:00:59', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b3973a84-7158-48e9-92a0-c1ffd7eb8dd7'	System	06 Sep 2020 17:01:34
User entered 'None (0)'	System	06 Sep 2020 17:01:34

FDA-CBER-2022-1614-0174679

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-06T12:01:01', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b3973a84-7158-48e9-92a0-c1ffd7eb8dd7'	System	06 Sep 2020 17:01:34
User entered 'None (0)'	System	06 Sep 2020 17:01:34

FDA-CBER-2022-1614-0174680

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-06T12:01:03', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b3973a84-7158-48e9-92a0-c1ffd7eb8dd7'	System	06 Sep 2020 17:01:34
User entered 'No (N)'	System	06 Sep 2020 17:01:34

FDA-CBER-2022-1614-0174681

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-06T12:01:06', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b3973a84-7158-48e9-92a0-c1ffd7eb8dd7'	System	06 Sep 2020 17:01:34
User entered '06 Sep 2020 12:01'	System	06 Sep 2020 17:01:34

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174683

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174684

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 7'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174685

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-07T13:05:53', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'da82dc7e-8070-426d-ad06-f53e348cf0f5'	System	07 Sep 2020 18:06:10
User entered 'None (0)'	System	07 Sep 2020 18:06:10

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-07T13:05:55', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'da82dc7e-8070-426d-ad06-f53e348cf0f5'	System	07 Sep 2020 18:06:10
User entered 'None (0)'	System	07 Sep 2020 18:06:10

FDA-CBER-2022-1614-0174687

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-07T13:05:56', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'da82dc7e-8070-426d-ad06-f53e348cf0f5'	System	07 Sep 2020 18:06:10
User entered 'None (0)'	System	07 Sep 2020 18:06:10

FDA-CBER-2022-1614-0174688

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-07T13:05:58', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'da82dc7e-8070-426d-ad06-f53e348cf0f5'	System	07 Sep 2020 18:06:10
User entered 'None (0)'	System	07 Sep 2020 18:06:10

FDA-CBER-2022-1614-0174689

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-07T13:05:59', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'da82dc7e-8070-426d-ad06-f53e348cf0f5'	System	07 Sep 2020 18:06:10
User entered 'None (0)'	System	07 Sep 2020 18:06:10

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-07T13:06:01', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'da82dc7e-8070-426d-ad06-f53e348cf0f5'	System	07 Sep 2020 18:06:10
User entered 'None (0)'	System	07 Sep 2020 18:06:10

FDA-CBER-2022-1614-0174691

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-07T13:06:05', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'da82dc7e-8070-426d-ad06-f53e348cf0f5'	System	07 Sep 2020 18:06:10
User entered 'No (N)'	System	07 Sep 2020 18:06:10

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-07T13:06:08', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'da82dc7e-8070-426d-ad06-f53e348cf0f5'	System	07 Sep 2020 18:06:10
User entered '07 Sep 2020 13:06'	System	07 Sep 2020 18:06:10

FDA-CBER-2022-1614-0174693

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174694

US3032343
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0174695

US3032343
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	10 Sep 2020 20:38:29

FDA-CBER-2022-1614-0174696

US3032343
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered '08 Sep 2020'	Samantha Wieseler (b) (4) (b) (4)	10 Sep 2020 20:38:29

FDA-CBER-2022-1614-0174697

US3032343
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Contact Made (CONTACT MADE)'	Samantha Wieseler (b) (4) (b) (4)	10 Sep 2020 20:38:29

FDA-CBER-2022-1614-0174698

US3032343
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	10 Sep 2020 20:38:29

FDA-CBER-2022-1614-0174699

US3032343
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	10 Sep 2020 20:38:33

US3032343
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered '1'	System	10 Sep 2020 20:38:33

FDA-CBER-2022-1614-0174701

US3032343
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:50:50
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	30 Nov 2020 23:06:20

FDA-CBER-2022-1614-0174702

US3032343
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:50:50
User entered '15 Sep 2020'	Linden DeBoer (b) (4) (b) (4)	30 Nov 2020 23:06:20

FDA-CBER-2022-1614-0174703

US3032343
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:50:50
User entered 'Contact Made (CONTACT MADE)'	Linden DeBoer (b) (4) (b) (4)	30 Nov 2020 23:06:20

FDA-CBER-2022-1614-0174704

US3032343
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:50:50
User entered empty.	Linden DeBoer (b) (4) (b) (4)	30 Nov 2020 23:06:20

FDA-CBER-2022-1614-0174705

US3032343
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:50:02

FDA-CBER-2022-1614-0174706

US3032343
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:46
User entered '1'	System	29 Sep 2020 14:50:02

FDA-CBER-2022-1614-0174707

US3032343
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:50:14

FDA-CBER-2022-1614-0174708

US3032343
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '22 Sep 2020'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:50:14

FDA-CBER-2022-1614-0174709

US3032343
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'Contact Made (CONTACT MADE)'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:50:14

FDA-CBER-2022-1614-0174710

US3032343
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered empty.	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:50:14

FDA-CBER-2022-1614-0174711

US3032343
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:50:19

FDA-CBER-2022-1614-0174712

US3032343
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '1'	System	29 Sep 2020 14:50:19

FDA-CBER-2022-1614-0174713

US3032343
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:50:31

FDA-CBER-2022-1614-0174714

US3032343
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '29 Sep 2020'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:50:31

FDA-CBER-2022-1614-0174715

US3032343
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'Clinic (Clinic)'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:50:31

FDA-CBER-2022-1614-0174716

US3032343
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'VISIT2'	System	29 Sep 2020 14:50:31

FDA-CBER-2022-1614-0174717

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:19

FDA-CBER-2022-1614-0174718

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:19

FDA-CBER-2022-1614-0174719

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '29 Sep 2020'	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:19

FDA-CBER-2022-1614-0174720

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '08:20'	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:19

FDA-CBER-2022-1614-0174721

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '29 Sep 2020 08:20'	System	29 Sep 2020 17:26:19

FDA-CBER-2022-1614-0174722

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '36.6' C	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:19

FDA-CBER-2022-1614-0174723

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:19

FDA-CBER-2022-1614-0174724

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:19

FDA-CBER-2022-1614-0174725

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '85'	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:19

FDA-CBER-2022-1614-0174726

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'bpm'	System	29 Sep 2020 17:26:19

FDA-CBER-2022-1614-0174727

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '16'	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:19

FDA-CBER-2022-1614-0174728

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'breaths/min'	System	29 Sep 2020 17:26:19

FDA-CBER-2022-1614-0174729

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '90'	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:19

FDA-CBER-2022-1614-0174730

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'mmHg'	System	29 Sep 2020 17:26:19

FDA-CBER-2022-1614-0174731

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '66'	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:19

FDA-CBER-2022-1614-0174732

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:56:17
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'mmHg'	System	29 Sep 2020 17:26:19

FDA-CBER-2022-1614-0174733

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:48

FDA-CBER-2022-1614-0174734

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:48

FDA-CBER-2022-1614-0174735

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '29 Sep 2020'	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:48

FDA-CBER-2022-1614-0174736

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '10:18'	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:48

FDA-CBER-2022-1614-0174737

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '29 Sep 2020 10:18'	System	29 Sep 2020 17:26:48

FDA-CBER-2022-1614-0174738

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '36.4' C	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:48

FDA-CBER-2022-1614-0174739

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:48

FDA-CBER-2022-1614-0174740

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:48

FDA-CBER-2022-1614-0174741

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '78'	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:48

FDA-CBER-2022-1614-0174742

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'bpm'	System	29 Sep 2020 17:26:48

FDA-CBER-2022-1614-0174743

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '14'	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:48

FDA-CBER-2022-1614-0174744

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'breaths/min'	System	29 Sep 2020 17:26:48

FDA-CBER-2022-1614-0174745

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '93'	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:48

FDA-CBER-2022-1614-0174746

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'mmHg'	System	29 Sep 2020 17:26:48

FDA-CBER-2022-1614-0174747

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '60'	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 17:26:48

FDA-CBER-2022-1614-0174748

US3032343
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:56:17
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'mmHg'	System	29 Sep 2020 17:26:48

FDA-CBER-2022-1614-0174749

US3032343
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:56:17
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:50:42

FDA-CBER-2022-1614-0174750

US3032343
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:56:17
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '29 Sep 2020'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:50:42

FDA-CBER-2022-1614-0174751

US3032343
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:50:50

FDA-CBER-2022-1614-0174752

US3032343
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '29 Sep 2020'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:50:50

FDA-CBER-2022-1614-0174753

US3032343
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'Urine (URINE)'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:50:50

FDA-CBER-2022-1614-0174754

US3032343
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'Negative (NEGATIVE)'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:50:50

FDA-CBER-2022-1614-0174755

US3032343
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:50:50

FDA-CBER-2022-1614-0174756

US3032343
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered empty.	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:50:50

FDA-CBER-2022-1614-0174757

US3032343
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered empty.	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:50:50

FDA-CBER-2022-1614-0174758

US3032343
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 21:56:17
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	29 Sep 2020 14:50:50

FDA-CBER-2022-1614-0174759

US3032343
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:56:17
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174760

US3032343
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:56:17
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered empty.	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174761

US3032343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered empty.	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:51:12

US3032343
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:56:17
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174763

US3032343
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:56:17
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '29 Sep 2020'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174764

US3032343
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:56:17
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '09:43'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174765

US3032343
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:56:17
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '29 Sep 2020 09:43'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174766

US3032343
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:56:17
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'Left Arm (LEFT ARM)'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174767

US3032343
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:56:17
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'ONCE'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174768

US3032343
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:56:17
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174769

US3032343
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:56:17
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:51:21

FDA-CBER-2022-1614-0174770

US3032343
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:56:17
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '29 Sep 2020'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:51:21

FDA-CBER-2022-1614-0174771

US3032343
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:56:17
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '08:52'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:51:21

FDA-CBER-2022-1614-0174772

US3032343
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:56:17
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '29 Sep 2020 08:52'	System	29 Sep 2020 14:51:21

FDA-CBER-2022-1614-0174773

US3032343
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 11 Aug 2021 21:56:17
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '29 Sep 2020'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:51:33

FDA-CBER-2022-1614-0174774

US3032343
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 21:56:17
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:51:33

FDA-CBER-2022-1614-0174775

US3032343
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 21:56:17
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:51:33

FDA-CBER-2022-1614-0174776

US3032343
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 21:56:17
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered '08:42'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:51:33

FDA-CBER-2022-1614-0174777

US3032343
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 21:56:17
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '29 Sep 2020 08:42'	System	29 Sep 2020 14:51:33

FDA-CBER-2022-1614-0174778

US3032343
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 21:56:17
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:51:33

FDA-CBER-2022-1614-0174779

US3032343
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 21:56:17
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:51:33

FDA-CBER-2022-1614-0174780

US3032343
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 21:56:17
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered empty.	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:51:33

FDA-CBER-2022-1614-0174781

US3032343
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 21:56:17
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	29 Sep 2020 14:51:33

FDA-CBER-2022-1614-0174782

US3032343
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	29 Sep 2020 18:38:01
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 14:51:36

FDA-CBER-2022-1614-0174783

US3032343
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '1'	System	29 Sep 2020 14:51:36

FDA-CBER-2022-1614-0174784

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174785

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T10:18:57', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '1d27d88c-6970-400a-8dc2-67daeaa0b138'	System	29 Sep 2020 15:19:10
User entered 'Yes (Y)'	System	29 Sep 2020 15:19:10

FDA-CBER-2022-1614-0174786

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T10:19:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '1d27d88c-6970-400a-8dc2-67daeaa0b138'	System	29 Sep 2020 15:19:10
User entered '97.5'	System	29 Sep 2020 15:19:10

FDA-CBER-2022-1614-0174787

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T10:19:04', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '1d27d88c-6970-400a-8dc2-67daeaa0b138'	System	29 Sep 2020 15:19:10
User entered 'No (N)'	System	29 Sep 2020 15:19:10

FDA-CBER-2022-1614-0174788

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T10:19:07', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '1d27d88c-6970-400a-8dc2-67daeaa0b138'	System	29 Sep 2020 15:19:10
User entered '29 Sep 2020 10:19'	System	29 Sep 2020 15:19:10

FDA-CBER-2022-1614-0174789

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '29 Sep 2020 10:03'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174790

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '29 Sep 2020 12:33'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174791

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174792

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T13:33:51', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b1ce92e2-0e06-4909-a03a-6271fce9db48'	System	29 Sep 2020 18:40:27
User entered 'Yes (Y)'	System	29 Sep 2020 18:40:27

FDA-CBER-2022-1614-0174793

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T13:33:55', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b1ce92e2-0e06-4909-a03a-6271fce9db48'	System	29 Sep 2020 18:40:27
User entered '98.5'	System	29 Sep 2020 18:40:27

FDA-CBER-2022-1614-0174794

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T13:33:59', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b1ce92e2-0e06-4909-a03a-6271fce9db48'	System	29 Sep 2020 18:40:27
User entered 'No (N)'	System	29 Sep 2020 18:40:27

FDA-CBER-2022-1614-0174795

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T13:34:02', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b1ce92e2-0e06-4909-a03a-6271fce9db48'	System	29 Sep 2020 18:40:27
User entered '29 Sep 2020 13:34'	System	29 Sep 2020 18:40:27

FDA-CBER-2022-1614-0174796

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '29 Sep 2020 13:28'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174797

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174798

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 2'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174799

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:56:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-30T12:12:01', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '16dc1e47-ed98-4c40-affb-73626b0036d3'	System	30 Sep 2020 17:12:19
User entered 'Yes (Y)'	System	30 Sep 2020 17:12:19

FDA-CBER-2022-1614-0174800

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:56:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-30T12:12:07', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '16dc1e47-ed98-4c40-affb-73626b0036d3'	System	30 Sep 2020 17:12:19
User entered '99.7'	System	30 Sep 2020 17:12:19

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:56:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-30T12:12:11', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '16dc1e47-ed98-4c40-affb-73626b0036d3'	System	30 Sep 2020 17:12:19
User entered 'No (N)'	System	30 Sep 2020 17:12:19

FDA-CBER-2022-1614-0174802

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-30T12:12:14', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '16dc1e47-ed98-4c40-affb-73626b0036d3'	System	30 Sep 2020 17:12:19
User entered '30 Sep 2020 12:12'	System	30 Sep 2020 17:12:19

FDA-CBER-2022-1614-0174803

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174804

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174805

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 3'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174806

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:56:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-01T12:00:20', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '55afadfb-1a01-4692-b054-c6ff50c8b38f'	System	01 Oct 2020 17:00:45
User entered 'Yes (Y)'	System	01 Oct 2020 17:00:45

FDA-CBER-2022-1614-0174807

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:56:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-01T12:00:29', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '55afadfb-1a01-4692-b054-c6ff50c8b38f'	System	01 Oct 2020 17:00:45
User entered '99.8'	System	01 Oct 2020 17:00:45

FDA-CBER-2022-1614-0174808

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:56:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-01T12:00:33', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '55afadfb-1a01-4692-b054-c6ff50c8b38f'	System	01 Oct 2020 17:00:45
User entered 'No (N)'	System	01 Oct 2020 17:00:45

FDA-CBER-2022-1614-0174809

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-01T12:00:35', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '55afadfb-1a01-4692-b054-c6ff50c8b38f'	System	01 Oct 2020 17:00:45
User entered '01 Oct 2020 12:00'	System	01 Oct 2020 17:00:45

FDA-CBER-2022-1614-0174810

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174811

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174812

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 4'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174813

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:56:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-02T13:17:11', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '7618a97f-f9a0-4a0a-9dbc-78f15428f7bd'	System	02 Oct 2020 18:17:27
User entered 'Yes (Y)'	System	02 Oct 2020 18:17:27

FDA-CBER-2022-1614-0174814

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:56:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-02T13:17:18', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '7618a97f-f9a0-4a0a-9dbc-78f15428f7bd'	System	02 Oct 2020 18:17:27
User entered '97.9'	System	02 Oct 2020 18:17:27

FDA-CBER-2022-1614-0174815

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:56:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-02T13:17:20', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '7618a97f-f9a0-4a0a-9dbc-78f15428f7bd'	System	02 Oct 2020 18:17:27
User entered 'No (N)'	System	02 Oct 2020 18:17:27

FDA-CBER-2022-1614-0174816

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-02T13:17:23', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '7618a97f-f9a0-4a0a-9dbc-78f15428f7bd'	System	02 Oct 2020 18:17:27
User entered '02 Oct 2020 13:17'	System	02 Oct 2020 18:17:27

FDA-CBER-2022-1614-0174817

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174818

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174819

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 5'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174820

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:56:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-03T12:47:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '13173551-dd3b-4a96-a80b-68f56ce08168'	System	03 Oct 2020 17:47:11
User entered 'Yes (Y)'	System	03 Oct 2020 17:47:11

FDA-CBER-2022-1614-0174821

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:56:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-03T12:47:05', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '13173551-dd3b-4a96-a80b-68f56ce08168'	System	03 Oct 2020 17:47:11
User entered '97.9'	System	03 Oct 2020 17:47:11

FDA-CBER-2022-1614-0174822

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:56:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-03T12:47:08', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '13173551-dd3b-4a96-a80b-68f56ce08168'	System	03 Oct 2020 17:47:11
User entered 'No (N)'	System	03 Oct 2020 17:47:11

FDA-CBER-2022-1614-0174823

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-03T12:47:10', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '13173551-dd3b-4a96-a80b-68f56ce08168'	System	03 Oct 2020 17:47:11
User entered '03 Oct 2020 12:47'	System	03 Oct 2020 17:47:11

FDA-CBER-2022-1614-0174824

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174825

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174826

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 6'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174827

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:56:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-04T14:20:36', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '4ed0a4a5-e683-4e3b-85bf-41b9fca0a6b9'	System	04 Oct 2020 19:20:51
User entered 'Yes (Y)'	System	04 Oct 2020 19:20:51

FDA-CBER-2022-1614-0174828

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:56:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-04T14:20:41', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '4ed0a4a5-e683-4e3b-85bf-41b9fca0a6b9'	System	04 Oct 2020 19:20:51
User entered '97.9'	System	04 Oct 2020 19:20:51

FDA-CBER-2022-1614-0174829

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:56:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-04T14:20:43', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '4ed0a4a5-e683-4e3b-85bf-41b9fca0a6b9'	System	04 Oct 2020 19:20:51
User entered 'No (N)'	System	04 Oct 2020 19:20:51

FDA-CBER-2022-1614-0174830

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-04T14:20:46', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '4ed0a4a5-e683-4e3b-85bf-41b9fca0a6b9'	System	04 Oct 2020 19:20:51
User entered '04 Oct 2020 14:20'	System	04 Oct 2020 19:20:51

FDA-CBER-2022-1614-0174831

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174832

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174833

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 7'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174834

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:56:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-05T12:00:15', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '851d2640-c6dc-43ce-bedf-4c3ef48253f6'	System	05 Oct 2020 17:00:32
User entered 'Yes (Y)'	System	05 Oct 2020 17:00:32

FDA-CBER-2022-1614-0174835

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:56:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-05T12:00:21', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '851d2640-c6dc-43ce-bedf-4c3ef48253f6'	System	05 Oct 2020 17:00:32
User entered '98.6'	System	05 Oct 2020 17:00:32

FDA-CBER-2022-1614-0174836

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:56:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD)', Time: '2020-10-05T12:00:24', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '851d2640-c6dc-43ce-bedf-4c3ef48253f6'	System	05 Oct 2020 17:00:32
User entered 'No (N)'	System	05 Oct 2020 17:00:32

FDA-CBER-2022-1614-0174837

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-05T12:00:27', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '851d2640-c6dc-43ce-bedf-4c3ef48253f6'	System	05 Oct 2020 17:00:32
User entered '05 Oct 2020 12:00'	System	05 Oct 2020 17:00:32

FDA-CBER-2022-1614-0174838

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174839

US3032343
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174840

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174841

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T10:19:13', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '13730225-8a0f-4c6f-9310-7220c972a82b'	System	29 Sep 2020 15:19:44
User entered 'None (1)'	System	29 Sep 2020 15:19:44

FDA-CBER-2022-1614-0174842

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T10:19:31', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '13730225-8a0f-4c6f-9310-7220c972a82b'	System	29 Sep 2020 15:19:44
User entered 'No (N)'	System	29 Sep 2020 15:19:44

FDA-CBER-2022-1614-0174843

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T10:19:36', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '13730225-8a0f-4c6f-9310-7220c972a82b'	System	29 Sep 2020 15:19:44
User entered 'No (N)'	System	29 Sep 2020 15:19:44

FDA-CBER-2022-1614-0174844

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T10:19:39', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '13730225-8a0f-4c6f-9310-7220c972a82b'	System	29 Sep 2020 15:19:44
User entered 'None (1)'	System	29 Sep 2020 15:19:44

FDA-CBER-2022-1614-0174845

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T10:19:41', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '13730225-8a0f-4c6f-9310-7220c972a82b'	System	29 Sep 2020 15:19:44
User entered '29 Sep 2020 10:19'	System	29 Sep 2020 15:19:44

FDA-CBER-2022-1614-0174846

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '29 Sep 2020 10:03'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174847

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '29 Sep 2020 12:33'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174848

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174849

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T13:34:11', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f7e69fca-9ccc-46f4-8e59-1260802a9935'	System	29 Sep 2020 18:41:04
User entered 'None (1)'	System	29 Sep 2020 18:41:04

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T13:34:21', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f7e69fca-9ccc-46f4-8e59-1260802a9935'	System	29 Sep 2020 18:41:04
User entered 'No (N)'	System	29 Sep 2020 18:41:04

FDA-CBER-2022-1614-0174851

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T13:34:30', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f7e69fca-9ccc-46f4-8e59-1260802a9935'	System	29 Sep 2020 18:41:04
User entered 'No (N)'	System	29 Sep 2020 18:41:04

FDA-CBER-2022-1614-0174852

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T13:34:35', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f7e69fca-9ccc-46f4-8e59-1260802a9935'	System	29 Sep 2020 18:41:04
User entered 'None (1)'	System	29 Sep 2020 18:41:04

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T13:34:37', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f7e69fca-9ccc-46f4-8e59-1260802a9935'	System	29 Sep 2020 18:41:04
User entered '29 Sep 2020 13:34'	System	29 Sep 2020 18:41:04

FDA-CBER-2022-1614-0174854

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '29 Sep 2020 13:28'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174855

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174856

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 2'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174857

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:56:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-30T12:12:26', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e120e20a-4bc9-43f6-b02b-c1f8cb28d419'	System	30 Sep 2020 17:12:47
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 17:12:47

FDA-CBER-2022-1614-0174858

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:56:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-30T12:12:29', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e120e20a-4bc9-43f6-b02b-c1f8cb28d419'	System	30 Sep 2020 17:12:47
User entered 'No (N)'	System	30 Sep 2020 17:12:47

FDA-CBER-2022-1614-0174859

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:56:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-30T12:12:37', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e120e20a-4bc9-43f6-b02b-c1f8cb28d419'	System	30 Sep 2020 17:12:47
User entered 'No (N)'	System	30 Sep 2020 17:12:47

FDA-CBER-2022-1614-0174860

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:56:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-30T12:12:41', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e120e20a-4bc9-43f6-b02b-c1f8cb28d419'	System	30 Sep 2020 17:12:47
User entered 'None (1)'	System	30 Sep 2020 17:12:47

FDA-CBER-2022-1614-0174861

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-30T12:12:44', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e120e20a-4bc9-43f6-b02b-c1f8cb28d419'	System	30 Sep 2020 17:12:47
User entered '30 Sep 2020 12:12'	System	30 Sep 2020 17:12:47

FDA-CBER-2022-1614-0174862

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174863

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174864

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 3'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174865

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:56:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-01T12:00:49', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '198223f0-1f4c-4423-9cc5-f9f475432817'	System	01 Oct 2020 17:02:09
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 17:02:09

FDA-CBER-2022-1614-0174866

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:56:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-01T12:00:53', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '198223f0-1f4c-4423-9cc5-f9f475432817'	System	01 Oct 2020 17:02:09
User entered 'No (N)'	System	01 Oct 2020 17:02:09

FDA-CBER-2022-1614-0174867

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:56:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-01T12:01:14', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '198223f0-1f4c-4423-9cc5-f9f475432817'	System	01 Oct 2020 17:02:09
User entered 'No (N)'	System	01 Oct 2020 17:02:09

FDA-CBER-2022-1614-0174868

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:56:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-01T12:01:17', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '198223f0-1f4c-4423-9cc5-f9f475432817'	System	01 Oct 2020 17:02:09
User entered 'None (1)'	System	01 Oct 2020 17:02:09

FDA-CBER-2022-1614-0174869

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-01T12:01:19', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '198223f0-1f4c-4423-9cc5-f9f475432817'	System	01 Oct 2020 17:02:09
User entered '01 Oct 2020 12:01'	System	01 Oct 2020 17:02:09

FDA-CBER-2022-1614-0174870

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174871

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174872

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 4'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174873

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:56:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-02T13:17:28', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '423ce1c4-a708-46a5-93ce-21297b53d9b3'	System	02 Oct 2020 18:17:54
User entered 'None (1)'	System	02 Oct 2020 18:17:54

FDA-CBER-2022-1614-0174874

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:56:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-02T13:17:33', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '423ce1c4-a708-46a5-93ce-21297b53d9b3'	System	02 Oct 2020 18:17:54
User entered 'No (N)'	System	02 Oct 2020 18:17:54

FDA-CBER-2022-1614-0174875

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:56:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-02T13:17:36', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '423ce1c4-a708-46a5-93ce-21297b53d9b3'	System	02 Oct 2020 18:17:54
User entered 'No (N)'	System	02 Oct 2020 18:17:54

FDA-CBER-2022-1614-0174876

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:56:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-02T13:17:39', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '423ce1c4-a708-46a5-93ce-21297b53d9b3'	System	02 Oct 2020 18:17:54
User entered 'None (1)'	System	02 Oct 2020 18:17:54

FDA-CBER-2022-1614-0174877

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-02T13:17:50', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '423ce1c4-a708-46a5-93ce-21297b53d9b3'	System	02 Oct 2020 18:17:54
User entered '02 Oct 2020 13:17'	System	02 Oct 2020 18:17:54

FDA-CBER-2022-1614-0174878

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174879

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174880

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 5'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174881

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:56:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-03T12:47:23', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f9c0eba0-887f-4a35-a4d6-db2584f36359'	System	03 Oct 2020 17:47:38
User entered 'None (1)'	System	03 Oct 2020 17:47:38

FDA-CBER-2022-1614-0174882

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:56:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-03T12:47:27', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f9c0eba0-887f-4a35-a4d6-db2584f36359'	System	03 Oct 2020 17:47:38
User entered 'No (N)'	System	03 Oct 2020 17:47:38

FDA-CBER-2022-1614-0174883

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:56:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD)', Time: '2020-10-03T12:47:31', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f9c0eba0-887f-4a35-a4d6-db2584f36359'	System	03 Oct 2020 17:47:38
User entered 'No (N)'	System	03 Oct 2020 17:47:38

FDA-CBER-2022-1614-0174884

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:56:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-03T12:47:34', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f9c0eba0-887f-4a35-a4d6-db2584f36359'	System	03 Oct 2020 17:47:38
User entered 'None (1)'	System	03 Oct 2020 17:47:38

FDA-CBER-2022-1614-0174885

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-03T12:47:36', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f9c0eba0-887f-4a35-a4d6-db2584f36359'	System	03 Oct 2020 17:47:38
User entered '03 Oct 2020 12:47'	System	03 Oct 2020 17:47:38

FDA-CBER-2022-1614-0174886

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174887

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174888

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 6'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174889

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:56:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-04T14:20:49', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '9766e899-310a-44a9-8681-63876bd489ba'	System	04 Oct 2020 19:21:02
User entered 'None (1)'	System	04 Oct 2020 19:21:02

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:56:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-04T14:20:52', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '9766e899-310a-44a9-8681-63876bd489ba'	System	04 Oct 2020 19:21:02
User entered 'No (N)'	System	04 Oct 2020 19:21:02

FDA-CBER-2022-1614-0174891

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:56:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-04T14:20:54', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '9766e899-310a-44a9-8681-63876bd489ba'	System	04 Oct 2020 19:21:02
User entered 'No (N)'	System	04 Oct 2020 19:21:02

FDA-CBER-2022-1614-0174892

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:56:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-04T14:20:56', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '9766e899-310a-44a9-8681-63876bd489ba'	System	04 Oct 2020 19:21:02
User entered 'None (1)'	System	04 Oct 2020 19:21:02

FDA-CBER-2022-1614-0174893

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-04T14:20:58', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '9766e899-310a-44a9-8681-63876bd489ba'	System	04 Oct 2020 19:21:02
User entered '04 Oct 2020 14:20'	System	04 Oct 2020 19:21:02

FDA-CBER-2022-1614-0174894

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174895

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174896

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 7'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174897

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:56:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-05T12:00:30', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bb7737a8-2a50-4b8e-8f5b-7db53657f72a'	System	05 Oct 2020 17:00:42
User entered 'None (1)'	System	05 Oct 2020 17:00:42

FDA-CBER-2022-1614-0174898

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:56:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-05T12:00:32', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bb7737a8-2a50-4b8e-8f5b-7db53657f72a'	System	05 Oct 2020 17:00:42
User entered 'No (N)'	System	05 Oct 2020 17:00:42

FDA-CBER-2022-1614-0174899

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:56:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-05T12:00:33', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bb7737a8-2a50-4b8e-8f5b-7db53657f72a'	System	05 Oct 2020 17:00:42
User entered 'No (N)'	System	05 Oct 2020 17:00:42

FDA-CBER-2022-1614-0174900

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:56:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-05T12:00:35', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bb7737a8-2a50-4b8e-8f5b-7db53657f72a'	System	05 Oct 2020 17:00:42
User entered 'None (1)'	System	05 Oct 2020 17:00:42

FDA-CBER-2022-1614-0174901

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:56:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-05T12:00:38', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bb7737a8-2a50-4b8e-8f5b-7db53657f72a'	System	05 Oct 2020 17:00:42
User entered '05 Oct 2020 12:00'	System	05 Oct 2020 17:00:42

FDA-CBER-2022-1614-0174902

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174903

US3032343
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174904

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174905

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T10:19:45', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '46a53306-e603-4f01-9552-0ef969138899'	System	29 Sep 2020 15:20:04
User entered 'None (0)'	System	29 Sep 2020 15:20:04

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T10:19:47', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '46a53306-e603-4f01-9552-0ef969138899'	System	29 Sep 2020 15:20:04
User entered 'None (0)'	System	29 Sep 2020 15:20:04

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T10:19:48', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '46a53306-e603-4f01-9552-0ef969138899'	System	29 Sep 2020 15:20:04
User entered 'None (0)'	System	29 Sep 2020 15:20:04

FDA-CBER-2022-1614-0174908

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T10:19:50', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '46a53306-e603-4f01-9552-0ef969138899'	System	29 Sep 2020 15:20:04
User entered 'None (0)'	System	29 Sep 2020 15:20:04

FDA-CBER-2022-1614-0174909

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T10:19:51', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '46a53306-e603-4f01-9552-0ef969138899'	System	29 Sep 2020 15:20:04
User entered 'None (0)'	System	29 Sep 2020 15:20:04

FDA-CBER-2022-1614-0174910

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T10:19:54', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '46a53306-e603-4f01-9552-0ef969138899'	System	29 Sep 2020 15:20:04
User entered 'None (0)'	System	29 Sep 2020 15:20:04

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T10:19:56', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '46a53306-e603-4f01-9552-0ef969138899'	System	29 Sep 2020 15:20:04
User entered 'No (N)'	System	29 Sep 2020 15:20:04

FDA-CBER-2022-1614-0174912

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T10:19:58', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '46a53306-e603-4f01-9552-0ef969138899'	System	29 Sep 2020 15:20:04
User entered '29 Sep 2020 10:19'	System	29 Sep 2020 15:20:04

FDA-CBER-2022-1614-0174913

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '29 Sep 2020 10:03'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174914

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '29 Sep 2020 12:33'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174915

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174916

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T13:34:42', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b2f49ab3-38c6-4ac9-b7ae-ce6ab6bb90aa'	System	29 Sep 2020 18:41:25
User entered 'None (0)'	System	29 Sep 2020 18:41:25

FDA-CBER-2022-1614-0174917

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T13:34:44', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b2f49ab3-38c6-4ac9-b7ae-ce6ab6bb90aa'	System	29 Sep 2020 18:41:25
User entered 'None (0)'	System	29 Sep 2020 18:41:25

FDA-CBER-2022-1614-0174918

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T13:34:48', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b2f49ab3-38c6-4ac9-b7ae-ce6ab6bb90aa'	System	29 Sep 2020 18:41:25
User entered 'None (0)'	System	29 Sep 2020 18:41:25

FDA-CBER-2022-1614-0174919

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T13:34:50', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b2f49ab3-38c6-4ac9-b7ae-ce6ab6bb90aa'	System	29 Sep 2020 18:41:25
User entered 'None (0)'	System	29 Sep 2020 18:41:25

FDA-CBER-2022-1614-0174920

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T13:34:53', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b2f49ab3-38c6-4ac9-b7ae-ce6ab6bb90aa'	System	29 Sep 2020 18:41:25
User entered 'None (0)'	System	29 Sep 2020 18:41:25

FDA-CBER-2022-1614-0174921

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T13:34:55', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b2f49ab3-38c6-4ac9-b7ae-ce6ab6bb90aa'	System	29 Sep 2020 18:41:25
User entered 'None (0)'	System	29 Sep 2020 18:41:25

FDA-CBER-2022-1614-0174922

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T13:34:58', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b2f49ab3-38c6-4ac9-b7ae-ce6ab6bb90aa'	System	29 Sep 2020 18:41:25
User entered 'No (N)'	System	29 Sep 2020 18:41:25

FDA-CBER-2022-1614-0174923

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-29T13:35:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b2f49ab3-38c6-4ac9-b7ae-ce6ab6bb90aa'	System	29 Sep 2020 18:41:25
User entered '29 Sep 2020 13:35'	System	29 Sep 2020 18:41:25

FDA-CBER-2022-1614-0174924

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '29 Sep 2020 13:28'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174925

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174926

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 2'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174927

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-30T12:12:51', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '9352cdad-9ea1-4f36-a399-02de3a618f6c'	System	30 Sep 2020 17:13:30
User entered 'No interference with activity (1)'	System	30 Sep 2020 17:13:30

FDA-CBER-2022-1614-0174928

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-30T12:12:54', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '9352cdad-9ea1-4f36-a399-02de3a618f6c'	System	30 Sep 2020 17:13:30
User entered 'None (0)'	System	30 Sep 2020 17:13:30

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD)', Time: '2020-09-30T12:13:04', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '9352cdad-9ea1-4f36-a399-02de3a618f6c'	System	30 Sep 2020 17:13:30
User entered 'Some interference with activity (2)'	System	30 Sep 2020 17:13:30

FDA-CBER-2022-1614-0174930

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-30T12:13:12', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '9352cdad-9ea1-4f36-a399-02de3a618f6c'	System	30 Sep 2020 17:13:30
User entered 'None (0)'	System	30 Sep 2020 17:13:30

FDA-CBER-2022-1614-0174931

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD)', Time: '2020-09-30T12:13:14', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '9352cdad-9ea1-4f36-a399-02de3a618f6c'	System	30 Sep 2020 17:13:30
User entered 'None (0)'	System	30 Sep 2020 17:13:30

FDA-CBER-2022-1614-0174932

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-30T12:13:20', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '9352cdad-9ea1-4f36-a399-02de3a618f6c'	System	30 Sep 2020 17:13:30
User entered 'Some interference with activity not requiring medical attention (2)'	System	30 Sep 2020 17:13:30

FDA-CBER-2022-1614-0174933

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-30T12:13:23', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '9352cdad-9ea1-4f36-a399-02de3a618f6c'	System	30 Sep 2020 17:13:30
User entered 'No (N)'	System	30 Sep 2020 17:13:30

FDA-CBER-2022-1614-0174934

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-09-30T12:13:26', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '9352cdad-9ea1-4f36-a399-02de3a618f6c'	System	30 Sep 2020 17:13:30
User entered '30 Sep 2020 12:13'	System	30 Sep 2020 17:13:30

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174936

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174937

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 3'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174938

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD)', Time: '2020-10-01T12:01:26', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'a22a7646-48ed-41d8-9e4d-f2469f780609'	System	01 Oct 2020 17:04:40
User entered 'No interference with activity (1)'	System	01 Oct 2020 17:04:40

FDA-CBER-2022-1614-0174939

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-01T12:01:30', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'a22a7646-48ed-41d8-9e4d-f2469f780609'	System	01 Oct 2020 17:04:40
User entered 'None (0)'	System	01 Oct 2020 17:04:40

FDA-CBER-2022-1614-0174940

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-01T12:01:37', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'a22a7646-48ed-41d8-9e4d-f2469f780609'	System	01 Oct 2020 17:04:40
User entered 'Some interference with activity (2)'	System	01 Oct 2020 17:04:40

FDA-CBER-2022-1614-0174941

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-01T12:01:48', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'a22a7646-48ed-41d8-9e4d-f2469f780609'	System	01 Oct 2020 17:04:40
User entered 'Some interference with activity (2)'	System	01 Oct 2020 17:04:40

FDA-CBER-2022-1614-0174942

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-01T12:01:50', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'a22a7646-48ed-41d8-9e4d-f2469f780609'	System	01 Oct 2020 17:04:40
User entered 'None (0)'	System	01 Oct 2020 17:04:40

FDA-CBER-2022-1614-0174943

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-01T12:01:57', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'a22a7646-48ed-41d8-9e4d-f2469f780609'	System	01 Oct 2020 17:04:40
User entered 'Some interference with activity not requiring medical attention (2)'	System	01 Oct 2020 17:04:40

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-01T12:03:26', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'a22a7646-48ed-41d8-9e4d-f2469f780609'	System	01 Oct 2020 17:04:40
User entered 'No (N)'	System	01 Oct 2020 17:04:40

FDA-CBER-2022-1614-0174945

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-01T12:03:30', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'a22a7646-48ed-41d8-9e4d-f2469f780609'	System	01 Oct 2020 17:04:40
User entered '01 Oct 2020 12:03'	System	01 Oct 2020 17:04:40

FDA-CBER-2022-1614-0174946

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174947

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174948

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 4'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174949

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-02T13:17:56', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '840e41a6-6c57-4cb0-a477-058435005022'	System	02 Oct 2020 18:18:17
User entered 'No interference with activity (1)'	System	02 Oct 2020 18:18:17

FDA-CBER-2022-1614-0174950

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-02T13:18:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '840e41a6-6c57-4cb0-a477-058435005022'	System	02 Oct 2020 18:18:17
User entered 'None (0)'	System	02 Oct 2020 18:18:17

FDA-CBER-2022-1614-0174951

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-02T13:18:02', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '840e41a6-6c57-4cb0-a477-058435005022'	System	02 Oct 2020 18:18:17
User entered 'None (0)'	System	02 Oct 2020 18:18:17

FDA-CBER-2022-1614-0174952

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-02T13:18:04', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '840e41a6-6c57-4cb0-a477-058435005022'	System	02 Oct 2020 18:18:17
User entered 'None (0)'	System	02 Oct 2020 18:18:17

FDA-CBER-2022-1614-0174953

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-02T13:18:05', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '840e41a6-6c57-4cb0-a477-058435005022'	System	02 Oct 2020 18:18:17
User entered 'None (0)'	System	02 Oct 2020 18:18:17

FDA-CBER-2022-1614-0174954

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-02T13:18:08', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '840e41a6-6c57-4cb0-a477-058435005022'	System	02 Oct 2020 18:18:17
User entered 'None (0)'	System	02 Oct 2020 18:18:17

FDA-CBER-2022-1614-0174955

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-02T13:18:11', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '840e41a6-6c57-4cb0-a477-058435005022'	System	02 Oct 2020 18:18:17
User entered 'No (N)'	System	02 Oct 2020 18:18:17

FDA-CBER-2022-1614-0174956

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-02T13:18:14', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '840e41a6-6c57-4cb0-a477-058435005022'	System	02 Oct 2020 18:18:17
User entered '02 Oct 2020 13:18'	System	02 Oct 2020 18:18:17

FDA-CBER-2022-1614-0174957

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174958

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174959

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 5'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174960

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-03T12:47:41', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b226807e-7572-46a8-b37c-9c875b62b50d'	System	03 Oct 2020 17:47:59
User entered 'No interference with activity (1)'	System	03 Oct 2020 17:47:59

FDA-CBER-2022-1614-0174961

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-03T12:47:43', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b226807e-7572-46a8-b37c-9c875b62b50d'	System	03 Oct 2020 17:47:59
User entered 'None (0)'	System	03 Oct 2020 17:47:59

FDA-CBER-2022-1614-0174962

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD)', Time: '2020-10-03T12:47:45', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b226807e-7572-46a8-b37c-9c875b62b50d'	System	03 Oct 2020 17:47:59
User entered 'None (0)'	System	03 Oct 2020 17:47:59

FDA-CBER-2022-1614-0174963

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD)', Time: '2020-10-03T12:47:47', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b226807e-7572-46a8-b37c-9c875b62b50d'	System	03 Oct 2020 17:47:59
User entered 'None (0)'	System	03 Oct 2020 17:47:59

FDA-CBER-2022-1614-0174964

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-03T12:47:50', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b226807e-7572-46a8-b37c-9c875b62b50d'	System	03 Oct 2020 17:47:59
User entered 'None (0)'	System	03 Oct 2020 17:47:59

FDA-CBER-2022-1614-0174965

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-03T12:47:52', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b226807e-7572-46a8-b37c-9c875b62b50d'	System	03 Oct 2020 17:47:59
User entered 'None (0)'	System	03 Oct 2020 17:47:59

FDA-CBER-2022-1614-0174966

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD)', Time: '2020-10-03T12:47:54', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b226807e-7572-46a8-b37c-9c875b62b50d'	System	03 Oct 2020 17:47:59
User entered 'No (N)'	System	03 Oct 2020 17:47:59

FDA-CBER-2022-1614-0174967

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-03T12:47:57', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'b226807e-7572-46a8-b37c-9c875b62b50d'	System	03 Oct 2020 17:47:59
User entered '03 Oct 2020 12:47'	System	03 Oct 2020 17:47:59

FDA-CBER-2022-1614-0174968

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174969

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174970

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 6'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174971

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-04T14:21:02', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e024c585-eb01-4ae3-b241-67b71468e430'	System	04 Oct 2020 19:21:19
User entered 'None (0)'	System	04 Oct 2020 19:21:19

FDA-CBER-2022-1614-0174972

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-04T14:21:04', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e024c585-eb01-4ae3-b241-67b71468e430'	System	04 Oct 2020 19:21:19
User entered 'None (0)'	System	04 Oct 2020 19:21:19

FDA-CBER-2022-1614-0174973

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-04T14:21:07', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e024c585-eb01-4ae3-b241-67b71468e430'	System	04 Oct 2020 19:21:19
User entered 'None (0)'	System	04 Oct 2020 19:21:19

FDA-CBER-2022-1614-0174974

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-04T14:21:08', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e024c585-eb01-4ae3-b241-67b71468e430'	System	04 Oct 2020 19:21:19
User entered 'None (0)'	System	04 Oct 2020 19:21:19

FDA-CBER-2022-1614-0174975

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-04T14:21:10', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e024c585-eb01-4ae3-b241-67b71468e430'	System	04 Oct 2020 19:21:19
User entered 'None (0)'	System	04 Oct 2020 19:21:19

FDA-CBER-2022-1614-0174976

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-04T14:21:12', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e024c585-eb01-4ae3-b241-67b71468e430'	System	04 Oct 2020 19:21:19
User entered 'None (0)'	System	04 Oct 2020 19:21:19

FDA-CBER-2022-1614-0174977

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-04T14:21:14', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e024c585-eb01-4ae3-b241-67b71468e430'	System	04 Oct 2020 19:21:19
User entered 'No (N)'	System	04 Oct 2020 19:21:19

FDA-CBER-2022-1614-0174978

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-04T14:21:17', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'e024c585-eb01-4ae3-b241-67b71468e430'	System	04 Oct 2020 19:21:19
User entered '04 Oct 2020 14:21'	System	04 Oct 2020 19:21:19

FDA-CBER-2022-1614-0174979

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174980

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174981

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	29 Sep 2020 14:51:12
User entered 'Day 7'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174982

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-05T12:00:42', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'c6e760fd-3771-4f9f-aa4e-a6a3c20bc048'	System	05 Oct 2020 17:00:55
User entered 'None (0)'	System	05 Oct 2020 17:00:55

FDA-CBER-2022-1614-0174983

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-05T12:00:43', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'c6e760fd-3771-4f9f-aa4e-a6a3c20bc048'	System	05 Oct 2020 17:00:55
User entered 'None (0)'	System	05 Oct 2020 17:00:55

FDA-CBER-2022-1614-0174984

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-05T12:00:44', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'c6e760fd-3771-4f9f-aa4e-a6a3c20bc048'	System	05 Oct 2020 17:00:55
User entered 'None (0)'	System	05 Oct 2020 17:00:55

FDA-CBER-2022-1614-0174985

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-05T12:00:45', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'c6e760fd-3771-4f9f-aa4e-a6a3c20bc048'	System	05 Oct 2020 17:00:55
User entered 'None (0)'	System	05 Oct 2020 17:00:55

FDA-CBER-2022-1614-0174986

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-05T12:00:47', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'c6e760fd-3771-4f9f-aa4e-a6a3c20bc048'	System	05 Oct 2020 17:00:55
User entered 'None (0)'	System	05 Oct 2020 17:00:55

FDA-CBER-2022-1614-0174987

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-05T12:00:49', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'c6e760fd-3771-4f9f-aa4e-a6a3c20bc048'	System	05 Oct 2020 17:00:55
User entered 'None (0)'	System	05 Oct 2020 17:00:55

FDA-CBER-2022-1614-0174988

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-05T12:00:50', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'c6e760fd-3771-4f9f-aa4e-a6a3c20bc048'	System	05 Oct 2020 17:00:55
User entered 'No (N)'	System	05 Oct 2020 17:00:55

FDA-CBER-2022-1614-0174989

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-10-05T12:00:52', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'c6e760fd-3771-4f9f-aa4e-a6a3c20bc048'	System	05 Oct 2020 17:00:55
User entered '05 Oct 2020 12:00'	System	05 Oct 2020 17:00:55

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174991

US3032343
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:56:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:51:12

FDA-CBER-2022-1614-0174992

US3032343
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:57:02
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	06 Oct 2020 14:53:13

FDA-CBER-2022-1614-0174993

US3032343
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:57:02
User entered '06 Oct 2020'	Samantha Wieseler (b) (4) (b) (4)	06 Oct 2020 14:53:13

FDA-CBER-2022-1614-0174994

US3032343
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:57:02
User entered 'Contact Made (CONTACT MADE)'	Samantha Wieseler (b) (4) (b) (4)	06 Oct 2020 14:53:13

FDA-CBER-2022-1614-0174995

US3032343
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:57:02
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	06 Oct 2020 14:53:13

FDA-CBER-2022-1614-0174996

US3032343
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:57:02
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	06 Oct 2020 14:54:04

FDA-CBER-2022-1614-0174997

US3032343
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '1'	System	06 Oct 2020 14:54:04

FDA-CBER-2022-1614-0174998

US3032343
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	14 Oct 2020 19:48:36
User entered 'Yes (Y)'	Chelsie Nutsch (b) (4) (b) (4)	13 Oct 2020 15:46:44

FDA-CBER-2022-1614-0174999

US3032343
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	14 Oct 2020 19:48:36
User entered '13 Oct 2020'	Chelsie Nutsch (b) (4) (b) (4)	13 Oct 2020 15:46:44

FDA-CBER-2022-1614-0175000

US3032343
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	14 Oct 2020 19:48:36
User entered 'Contact Made (CONTACT MADE)'	Chelsie Nutsch (b) (4) (b) (4)	13 Oct 2020 15:46:44

FDA-CBER-2022-1614-0175001

US3032343
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	14 Oct 2020 19:48:36
User entered empty.	Chelsie Nutsch (b) (4) (b) (4)	13 Oct 2020 15:46:44

US3032343
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	14 Oct 2020 19:48:36
User entered 'Yes (Y)'	Chelsie Nutsch (b) (4) (b) (4)	13 Oct 2020 15:46:50

US3032343
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '1'	System	13 Oct 2020 15:46:50

FDA-CBER-2022-1614-0175004

US3032343
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	22 Oct 2020 15:09:15
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Oct 2020 16:29:09

US3032343
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:46:59
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	22 Oct 2020 19:56:17
User entered '22 Oct 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	22 Oct 2020 19:56:17
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	22 Oct 2020 19:56:13
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	22 Oct 2020 19:56:13
User entered '23 Oct 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	22 Oct 2020 19:56:13
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	22 Oct 2020 15:09:15
User entered '20 Oct 2020'	Kelsey Kelley (b) (4) (b) (4)	21 Oct 2020 16:29:09

US3032343
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	22 Oct 2020 15:09:15
User entered 'Contact Made (CONTACT MADE)'	Kelsey Kelley (b) (4) (b) (4)	21 Oct 2020 16:29:09

FDA-CBER-2022-1614-0175007

US3032343
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	22 Oct 2020 15:09:15
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Oct 2020 16:29:09

US3032343
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	22 Oct 2020 15:09:15
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Oct 2020 16:29:11

FDA-CBER-2022-1614-0175009

US3032343
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '1'	System	21 Oct 2020 16:29:11

FDA-CBER-2022-1614-0175010

US3032343
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:46:59
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 14:05:48

FDA-CBER-2022-1614-0175011

US3032343
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:46:59
User entered '27 Oct 2020'	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 14:05:48

FDA-CBER-2022-1614-0175012

US3032343
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:46:59
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 14:05:48

FDA-CBER-2022-1614-0175013

US3032343
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'VISIT3'	System	27 Oct 2020 14:05:48

FDA-CBER-2022-1614-0175014

US3032343
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:46:59
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 14:14:00

US3032343
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:46:59
User entered '27 Oct 2020'	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 14:14:00

FDA-CBER-2022-1614-0175016

US3032343
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:46:59
User entered '08:30'	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 14:14:00

FDA-CBER-2022-1614-0175017

US3032343
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '27 Oct 2020 08:30'	System	27 Oct 2020 14:14:00

FDA-CBER-2022-1614-0175018

US3032343
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:46:59
User entered '37.1' C	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 14:14:00

FDA-CBER-2022-1614-0175019

US3032343
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:46:59
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 14:14:00

FDA-CBER-2022-1614-0175020

US3032343
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:46:59
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 14:14:00

FDA-CBER-2022-1614-0175021

US3032343
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:46:59
User entered '91'	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 14:14:00

FDA-CBER-2022-1614-0175022

US3032343
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'bpm'	System	27 Oct 2020 14:14:00

FDA-CBER-2022-1614-0175023

US3032343
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:46:59
User entered '16'	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 14:14:00

FDA-CBER-2022-1614-0175024

US3032343
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'breaths/min'	System	27 Oct 2020 14:14:00

FDA-CBER-2022-1614-0175025

US3032343
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:46:59
User entered '90'	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 14:14:00

FDA-CBER-2022-1614-0175026

US3032343
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'mmHg'	System	27 Oct 2020 14:14:00

FDA-CBER-2022-1614-0175027

US3032343
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:46:59
User entered '69'	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 14:14:00

FDA-CBER-2022-1614-0175028

US3032343
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'mmHg'	System	27 Oct 2020 14:14:00

FDA-CBER-2022-1614-0175029

US3032343
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25

FDA-CBER-2022-1614-0175030

US3032343
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25

FDA-CBER-2022-1614-0175031

US3032343
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:56:17
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:46:59
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 14:14:15

FDA-CBER-2022-1614-0175032

US3032343
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:56:17
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:46:59
User entered '27 Oct 2020'	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 14:14:15

FDA-CBER-2022-1614-0175033

US3032343
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:56:17
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:46:59
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 14:14:50

US3032343
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:56:17
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:46:59
User entered '27 Oct 2020'	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 14:14:50

FDA-CBER-2022-1614-0175035

US3032343
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:56:17
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:46:59
User entered '08:37'	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 14:14:50

FDA-CBER-2022-1614-0175036

US3032343
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:56:17
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '27 Oct 2020 08:37'	System	27 Oct 2020 14:14:50

FDA-CBER-2022-1614-0175037

US3032343
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23FEB2021 is reported under OL-1 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 OL-D1 Visit on Immunogenicity Assessment page.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 10:42:11
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23FEB2021 is reported under OL-1 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 OL-D1 Visit on Immunogenicity Assessment page.' answered with 'marked in EDC' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	23 Mar 2021 17:15:07
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23FEB2021 is reported under OL-1 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 OL-D1 Visit on Immunogenicity Assessment page.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:30:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:46:59
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 14:14:54

FDA-CBER-2022-1614-0175038

US3032343
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '1'	System	27 Oct 2020 14:14:54

FDA-CBER-2022-1614-0175039

US3032343
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 64'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0175040

US3032343

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-11-01T00:11:52', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '832a25a1-4da4-4bec-8a37-2e199999f21b'	System	01 Nov 2020 05:12:16
User entered 'No (N)'	System	01 Nov 2020 05:12:16

US3032343

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-11-01T00:12:04', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '832a25a1-4da4-4bec-8a37-2e199999f21b'	System	01 Nov 2020 05:12:16
User entered 'No (N)'	System	01 Nov 2020 05:12:16

US3032343
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-11-01T00:12:12', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '832a25a1-4da4-4bec-8a37-2e199999f21b'	System	01 Nov 2020 05:12:16
User entered '01 Nov 2020 00:12:12'	System	01 Nov 2020 05:12:16

FDA-CBER-2022-1614-0175043

US3032343
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0175044

US3032343
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0175045

US3032343
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 71'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0175046

US3032343

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-11-08T16:59:31', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bfdd65c4-2c7f-41d9-abe7-e404907c943c'	System	08 Nov 2020 22:59:52
User entered 'No (N)'	System	08 Nov 2020 22:59:52

US3032343

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-11-08T16:59:45', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bfdd65c4-2c7f-41d9-abe7-e404907c943c'	System	08 Nov 2020 22:59:52
User entered 'No (N)'	System	08 Nov 2020 22:59:52

US3032343
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-11-08T16:59:50', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'bfdd65c4-2c7f-41d9-abe7-e404907c943c'	System	08 Nov 2020 22:59:52
User entered '08 Nov 2020 16:59:50'	System	08 Nov 2020 22:59:52

FDA-CBER-2022-1614-0175049

US3032343
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0175050

US3032343
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0175051

US3032343
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered 'Day 78'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0175052

US3032343

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-11-15T00:46:11', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '62bbc76e-4cae-4741-87a2-767b6cbc030c'	System	15 Nov 2020 06:46:27
User entered 'No (N)'	System	15 Nov 2020 06:46:27

US3032343

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-11-15T00:46:21', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '62bbc76e-4cae-4741-87a2-767b6cbc030c'	System	15 Nov 2020 06:46:27
User entered 'No (N)'	System	15 Nov 2020 06:46:27

US3032343
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-11-15T00:46:24', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '62bbc76e-4cae-4741-87a2-767b6cbc030c'	System	15 Nov 2020 06:46:27
User entered '15 Nov 2020 00:46:24'	System	15 Nov 2020 06:46:27

FDA-CBER-2022-1614-0175055

US3032343
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0175056

US3032343
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:13:16
Data entry locked.	System	01 Sep 2020 16:28:03
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 16:28:03

FDA-CBER-2022-1614-0175057

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175058

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-11-22T09:19:12', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '19ae7224-4202-4af0-ae11-9060dd286426'	System	22 Nov 2020 15:19:25
User entered 'No (N)'	System	22 Nov 2020 15:19:25

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-11-22T09:19:19', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '19ae7224-4202-4af0-ae11-9060dd286426'	System	22 Nov 2020 15:19:25
User entered 'No (N)'	System	22 Nov 2020 15:19:25

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-11-22T09:19:22', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '19ae7224-4202-4af0-ae11-9060dd286426'	System	22 Nov 2020 15:19:25
User entered '22 Nov 2020 09:19:22'	System	22 Nov 2020 15:19:25

FDA-CBER-2022-1614-0175061

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175062

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175063

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175064

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-11-26T00:17:32', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '6a2e92de-33f3-40d0-b2ff-a6e731ea1bf4'	System	26 Nov 2020 06:17:43
User entered 'No (N)'	System	26 Nov 2020 06:17:43

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-11-26T00:17:36', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '6a2e92de-33f3-40d0-b2ff-a6e731ea1bf4'	System	26 Nov 2020 06:17:43
User entered 'No (N)'	System	26 Nov 2020 06:17:43

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-11-26T00:17:38', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '6a2e92de-33f3-40d0-b2ff-a6e731ea1bf4'	System	26 Nov 2020 06:17:43
User entered '26 Nov 2020 00:17:38'	System	26 Nov 2020 06:17:43

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175068

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175069

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175070

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-12-04T06:27:41', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '55689a2d-8dbe-408a-9010-47e16d049a4c'	System	04 Dec 2020 12:28:15
User entered 'Yes (Y)'	System	04 Dec 2020 12:28:15

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-12-04T06:27:46', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '55689a2d-8dbe-408a-9010-47e16d049a4c'	System	04 Dec 2020 12:28:15
User entered 'No (N)'	System	04 Dec 2020 12:28:15

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-12-04T06:27:53', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '55689a2d-8dbe-408a-9010-47e16d049a4c'	System	04 Dec 2020 12:28:15
User entered 'No (N)'	System	04 Dec 2020 12:28:15

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-12-04T06:28:06', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '55689a2d-8dbe-408a-9010-47e16d049a4c'	System	04 Dec 2020 12:28:15
User entered 'No (N)'	System	04 Dec 2020 12:28:15

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-12-04T06:28:13', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '55689a2d-8dbe-408a-9010-47e16d049a4c'	System	04 Dec 2020 12:28:15
User entered '04 Dec 2020 06:28:13'	System	04 Dec 2020 12:28:15

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175076

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175077

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175078

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-12-10T01:32:46', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '192c7f26-68fa-41dd-a32f-cd291e0549ee'	System	10 Dec 2020 07:32:57
User entered 'No (N)'	System	10 Dec 2020 07:32:57

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-12-10T01:32:51', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '192c7f26-68fa-41dd-a32f-cd291e0549ee'	System	10 Dec 2020 07:32:57
User entered 'No (N)'	System	10 Dec 2020 07:32:57

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-12-10T01:32:55', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '192c7f26-68fa-41dd-a32f-cd291e0549ee'	System	10 Dec 2020 07:32:57
User entered '10 Dec 2020 01:32:55'	System	10 Dec 2020 07:32:57

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175082

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175083

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175084

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-12-17T00:14:05', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f34727ea-cd1b-4908-b87a-b7c8495d1e5f'	System	17 Dec 2020 06:14:12
User entered 'No (N)'	System	17 Dec 2020 06:14:12

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-12-17T00:14:08', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f34727ea-cd1b-4908-b87a-b7c8495d1e5f'	System	17 Dec 2020 06:14:12
User entered 'No (N)'	System	17 Dec 2020 06:14:12

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-12-17T00:14:11', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f34727ea-cd1b-4908-b87a-b7c8495d1e5f'	System	17 Dec 2020 06:14:12
User entered '17 Dec 2020 00:14:11'	System	17 Dec 2020 06:14:12

FDA-CBER-2022-1614-0175087

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175088

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175089

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175090

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-12-24T00:01:32', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '8cee2d68-1e2b-4d39-8ab6-e5a7eb20a66c'	System	24 Dec 2020 06:02:46
User entered 'No (N)'	System	24 Dec 2020 06:02:46

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-12-24T00:01:34', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '8cee2d68-1e2b-4d39-8ab6-e5a7eb20a66c'	System	24 Dec 2020 06:02:46
User entered 'No (N)'	System	24 Dec 2020 06:02:46

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-12-24T00:02:37', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '8cee2d68-1e2b-4d39-8ab6-e5a7eb20a66c'	System	24 Dec 2020 06:02:46
User entered '24 Dec 2020 00:02:37'	System	24 Dec 2020 06:02:46

FDA-CBER-2022-1614-0175093

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175094

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175095

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175096

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-12-31T00:41:21', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '97b74941-cebe-4817-a70c-e2b26a3cd92c'	System	31 Dec 2020 06:41:28
User entered 'No (N)'	System	31 Dec 2020 06:41:28

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-12-31T00:41:23', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '97b74941-cebe-4817-a70c-e2b26a3cd92c'	System	31 Dec 2020 06:41:28
User entered 'No (N)'	System	31 Dec 2020 06:41:28

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2020-12-31T00:41:25', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '97b74941-cebe-4817-a70c-e2b26a3cd92c'	System	31 Dec 2020 06:41:28
User entered '31 Dec 2020 00:41:25'	System	31 Dec 2020 06:41:28

FDA-CBER-2022-1614-0175099

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175100

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175101

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175102

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-01-07T00:13:47', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '4337a379-461e-4dac-ad27-d38b264e65b2'	System	07 Jan 2021 06:13:56
User entered 'No (N)'	System	07 Jan 2021 06:13:56

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-01-07T00:13:49', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '4337a379-461e-4dac-ad27-d38b264e65b2'	System	07 Jan 2021 06:13:56
User entered 'No (N)'	System	07 Jan 2021 06:13:56

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-01-07T00:13:51', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '4337a379-461e-4dac-ad27-d38b264e65b2'	System	07 Jan 2021 06:13:56
User entered '07 Jan 2021 00:13:51'	System	07 Jan 2021 06:13:56

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175106

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175107

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175108

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-01-14T00:01:49', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '99d47c61-b31a-4ca6-8aa8-8b118691f51a'	System	14 Jan 2021 06:01:57
User entered 'No (N)'	System	14 Jan 2021 06:01:57

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-01-14T00:01:50', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '99d47c61-b31a-4ca6-8aa8-8b118691f51a'	System	14 Jan 2021 06:01:57
User entered 'No (N)'	System	14 Jan 2021 06:01:57

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-01-14T00:01:53', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '99d47c61-b31a-4ca6-8aa8-8b118691f51a'	System	14 Jan 2021 06:01:57
User entered '14 Jan 2021 00:01:53'	System	14 Jan 2021 06:01:57

FDA-CBER-2022-1614-0175111

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175112

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175113

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175114

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-01-21T00:34:51', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '4b33ef04-d923-421b-b759-7b04d0391b53'	System	21 Jan 2021 06:34:58
User entered 'No (N)'	System	21 Jan 2021 06:34:58

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-01-21T00:34:54', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '4b33ef04-d923-421b-b759-7b04d0391b53'	System	21 Jan 2021 06:34:58
User entered 'No (N)'	System	21 Jan 2021 06:34:58

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-01-21T00:34:56', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '4b33ef04-d923-421b-b759-7b04d0391b53'	System	21 Jan 2021 06:34:58
User entered '21 Jan 2021 00:34:56'	System	21 Jan 2021 06:34:58

FDA-CBER-2022-1614-0175117

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175118

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175119

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175120

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-01-28T01:59:14', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '48d1505a-8024-44a1-b8c1-e14a7c1fc428'	System	28 Jan 2021 07:59:25
User entered 'No (N)'	System	28 Jan 2021 07:59:25

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-01-28T01:59:17', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '48d1505a-8024-44a1-b8c1-e14a7c1fc428'	System	28 Jan 2021 07:59:25
User entered 'No (N)'	System	28 Jan 2021 07:59:25

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-01-28T01:59:23', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '48d1505a-8024-44a1-b8c1-e14a7c1fc428'	System	28 Jan 2021 07:59:25
User entered '28 Jan 2021 01:59:23'	System	28 Jan 2021 07:59:25

FDA-CBER-2022-1614-0175123

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175124

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175125

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175126

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-02-04T00:53:36', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'cd464113-0fbf-4f79-9390-4833f4a00d0c'	System	04 Feb 2021 06:53:44
User entered 'No (N)'	System	04 Feb 2021 06:53:44

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-02-04T00:53:38', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'cd464113-0fbf-4f79-9390-4833f4a00d0c'	System	04 Feb 2021 06:53:44
User entered 'No (N)'	System	04 Feb 2021 06:53:44

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-02-04T00:53:40', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'cd464113-0fbf-4f79-9390-4833f4a00d0c'	System	04 Feb 2021 06:53:44
User entered '04 Feb 2021 00:53:40'	System	04 Feb 2021 06:53:44

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175130

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175131

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175132

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-02-11T00:24:15', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f0bda05a-323d-4b65-ba91-5d0e2ae057f6'	System	11 Feb 2021 06:24:31
User entered 'No (N)'	System	11 Feb 2021 06:24:31

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-02-11T00:24:23', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f0bda05a-323d-4b65-ba91-5d0e2ae057f6'	System	11 Feb 2021 06:24:31
User entered 'No (N)'	System	11 Feb 2021 06:24:31

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-02-11T00:24:28', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'f0bda05a-323d-4b65-ba91-5d0e2ae057f6'	System	11 Feb 2021 06:24:31
User entered '11 Feb 2021 00:24:28'	System	11 Feb 2021 06:24:31

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175136

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175137

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175138

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-02-18T00:21:53', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '92fdc9ab-4dc7-4b8e-8659-2515806e525a'	System	18 Feb 2021 06:22:01
User entered 'No (N)'	System	18 Feb 2021 06:22:01

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-02-18T00:21:55', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '92fdc9ab-4dc7-4b8e-8659-2515806e525a'	System	18 Feb 2021 06:22:01
User entered 'No (N)'	System	18 Feb 2021 06:22:01

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-02-18T00:21:58', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '92fdc9ab-4dc7-4b8e-8659-2515806e525a'	System	18 Feb 2021 06:22:01
User entered '18 Feb 2021 00:21:58'	System	18 Feb 2021 06:22:01

FDA-CBER-2022-1614-0175141

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175142

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175143

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175144

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-02-25T00:30:02-06:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'dff8473b-81f6-49d9-a302-8259cf146bd6'	System	25 Feb 2021 06:30:11
User entered 'No (N)'	System	25 Feb 2021 06:30:11

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-02-25T00:30:04-06:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'dff8473b-81f6-49d9-a302-8259cf146bd6'	System	25 Feb 2021 06:30:11
User entered 'No (N)'	System	25 Feb 2021 06:30:11

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-02-25T00:30:07-06:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'dff8473b-81f6-49d9-a302-8259cf146bd6'	System	25 Feb 2021 06:30:11
User entered '25 Feb 2021 06:30:07'	System	25 Feb 2021 06:30:11

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175148

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175149

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175150

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-03-04T00:22:32-06:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '3cc1d3bf-138c-4e45-88b3-1cc9077617e1'	System	04 Mar 2021 06:23:27
User entered 'No (N)'	System	04 Mar 2021 06:23:27

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-03-04T00:22:35-06:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '3cc1d3bf-138c-4e45-88b3-1cc9077617e1'	System	04 Mar 2021 06:23:27
User entered 'No (N)'	System	04 Mar 2021 06:23:27

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-03-04T00:23:19-06:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '3cc1d3bf-138c-4e45-88b3-1cc9077617e1'	System	04 Mar 2021 06:23:27
User entered '04 Mar 2021 00:23:19'	System	04 Mar 2021 06:23:27

FDA-CBER-2022-1614-0175153

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175154

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175155

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175156

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-03-11T00:43:55-06:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '247aab39-da47-4079-8131-640c6234cc41'	System	11 Mar 2021 06:44:04
User entered 'No (N)'	System	11 Mar 2021 06:44:04

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-03-11T00:43:58-06:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '247aab39-da47-4079-8131-640c6234cc41'	System	11 Mar 2021 06:44:04
User entered 'No (N)'	System	11 Mar 2021 06:44:04

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-03-11T00:44:00-06:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '247aab39-da47-4079-8131-640c6234cc41'	System	11 Mar 2021 06:44:04
User entered '11 Mar 2021 00:44:00'	System	11 Mar 2021 06:44:04

FDA-CBER-2022-1614-0175159

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175160

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175161

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:37:01

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-03-18T00:02:14-05:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'a3b2de81-0d4d-463d-829b-dd1205f49864'	System	18 Mar 2021 05:02:23
User entered 'No (N)'	System	18 Mar 2021 05:02:23

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-03-18T00:02:17-05:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'a3b2de81-0d4d-463d-829b-dd1205f49864'	System	18 Mar 2021 05:02:23
User entered 'No (N)'	System	18 Mar 2021 05:02:23

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-03-18T00:02:19-05:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: 'a3b2de81-0d4d-463d-829b-dd1205f49864'	System	18 Mar 2021 05:02:23
User entered '18 Mar 2021 00:02:19'	System	18 Mar 2021 05:02:23

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175166

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175167

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175168

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-03-27T19:49:21-05:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '43abb335-1c57-45db-afd4-c9dd62613825'	System	28 Mar 2021 00:49:29
User entered 'No (N)'	System	28 Mar 2021 00:49:29

US3032343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:17

Have you been exposed to someone with 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 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-03-27T19:49:24-05:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '43abb335-1c57-45db-afd4-c9dd62613825'	System	28 Mar 2021 00:49:29
User entered 'No (N)'	System	28 Mar 2021 00:49:29

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-03-27T19:49:27-05:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '43abb335-1c57-45db-afd4-c9dd62613825'	System	28 Mar 2021 00:49:29
User entered '27 Mar 2021 19:49:27'	System	28 Mar 2021 00:49:29

FDA-CBER-2022-1614-0175171

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 21:37:01

US3032343
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:56:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:37:01
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 21:37:01

FDA-CBER-2022-1614-0175173

US3032343

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:56:17

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-03-04T00:23:29-06:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '3b04924e-88f3-4710-9f0b-c74079f41bbc'	System	04 Mar 2021 06:23:35
User entered 'No (N)'	System	04 Mar 2021 06:23:35

US3032343
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary (1)
Generated On: 11 Aug 2021 21:56:17
Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BBD830E-F4CA-4DAE-A53B-7DB37BE5ACBD) ', Time: '2021-03-04T00:23:33-06:00', User OID: 'PatientReportedOutcome (US3032343)', ODM File OID: '3b04924e-88f3-4710-9f0b-c74079f41bbc'	System	04 Mar 2021 06:23:35
User entered '04 Mar 2021 00:23:33'	System	04 Mar 2021 06:23:35

FDA-CBER-2022-1614-0175175

US3032343
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:08:34

FDA-CBER-2022-1614-0175176

US3032343
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
Signature has been broken.	Chelsie Nutsch (b) (4) (b) (4)	22 Mar 2021 19:25:17
User entered '25 Nov 2020' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4)	22 Mar 2021 19:25:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:32:09
User entered '23 Nov 2020'	(b) (4), (b) (6)	13 Jan 2021 16:08:34

FDA-CBER-2022-1614-0175177

US3032343
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:08:34

FDA-CBER-2022-1614-0175178

US3032343
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:32:09
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 16:08:34

FDA-CBER-2022-1614-0175179

US3032343
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:08:38

US3032343
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '1'	System	13 Jan 2021 16:08:38

FDA-CBER-2022-1614-0175181

US3032343
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:08:56

US3032343
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User closed query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 23FEB2021 is reported under Participant Decision Visit / OL-D1 in PPD Central lab, however the same is missing in EDC. Please confirm if visit is performed on 23FEB2021, if yes sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).		29 Mar 2021 06:04:01
Query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 23FEB2021 is reported under Participant Decision Visit / OL-D1 in PPD Central lab, however the same is missing in EDC. Please confirm if visit is performed on 23FEB2021, if yes sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'corrected. thank you' (Site from DM).	Chelsie Nutsch (b) (4) (b) (4)	22 Mar 2021 19:29:48
User opened query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 23FEB2021 is reported under Participant Decision Visit / OL-D1 in PPD Central lab, however the same is missing in EDC. Please confirm if visit is performed on 23FEB2021, if yes sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 04:54:53
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:32:09
User entered '28 Dec 2020'	(b) (4), (b) (6)	13 Jan 2021 16:08:56

FDA-CBER-2022-1614-0175183

US3032343
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
Signature has been broken.	Chelsie Nutsch (b) (4) (b) (4)	22 Mar 2021 19:29:17
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4)	22 Mar 2021 19:29:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:32:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Jan 2021 16:08:56

US3032343
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
Signature has been broken.	Chelsie Nutsch (b) (4) (b) (4)	22 Mar 2021 19:29:17
User entered 'subject contacted site 11Jan2021 to finish safety call. no changes with subject.' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4)	22 Mar 2021 19:29:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:32:09
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 16:08:56

US3032343
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:09:01

FDA-CBER-2022-1614-0175186

US3032343
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '1'	System	13 Jan 2021 16:09:01

FDA-CBER-2022-1614-0175187

US3032343
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Mar 2021 21:48:31
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	12 Mar 2021 19:54:49

US3032343
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
Signature has been broken.	Chelsie Nutsch (b) (4) (b) (4)	22 Mar 2021 19:30:52
User entered '29 Jan 2021' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4)	22 Mar 2021 19:30:52
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Mar 2021 21:48:31
User entered '25 Jan 2021'	Samantha Wieseler (b) (4) (b) (4)	12 Mar 2021 19:54:49

US3032343
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Mar 2021 21:48:31
User entered 'Contact Made (CONTACT MADE)'	Samantha Wieseler (b) (4) (b) (4)	12 Mar 2021 19:54:49

FDA-CBER-2022-1614-0175190

US3032343
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Mar 2021 21:48:31
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	12 Mar 2021 19:54:49

FDA-CBER-2022-1614-0175191

US3032343
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Mar 2021 21:48:31
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	12 Mar 2021 19:54:52

FDA-CBER-2022-1614-0175192

US3032343
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '1'	System	12 Mar 2021 19:54:52

FDA-CBER-2022-1614-0175193

US3032343
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Mar 2021 21:48:31
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	18 Mar 2021 15:40:08

FDA-CBER-2022-1614-0175194

US3032343
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Mar 2021 21:48:31
User entered '23 Feb 2021'	Linden DeBoer (b) (4) (b) (4)	18 Mar 2021 15:40:08

FDA-CBER-2022-1614-0175195

US3032343
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Mar 2021 21:48:31
User entered 'Contact Made (CONTACT MADE)'	Linden DeBoer (b) (4) (b) (4)	18 Mar 2021 15:40:08

FDA-CBER-2022-1614-0175196

US3032343
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:56:17
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Mar 2021 21:48:31
User entered empty.	Linden DeBoer (b) (4) (b) (4)	18 Mar 2021 15:40:08

US3032343
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Mar 2021 21:48:31
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	18 Mar 2021 15:40:12

US3032343
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '1'	System	18 Mar 2021 15:40:12

FDA-CBER-2022-1614-0175199

US3032343
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:52:23

FDA-CBER-2022-1614-0175200

US3032343
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '30 Mar 2021'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:52:23

FDA-CBER-2022-1614-0175201

US3032343
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:52:23

FDA-CBER-2022-1614-0175202

US3032343
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'VISIT4'	System	30 Mar 2021 15:52:23

FDA-CBER-2022-1614-0175203

US3032343
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:52:34

FDA-CBER-2022-1614-0175204

US3032343
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:52:34

FDA-CBER-2022-1614-0175205

US3032343
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:52:34

FDA-CBER-2022-1614-0175206

US3032343
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	30 Mar 2021 15:52:34

FDA-CBER-2022-1614-0175207

US3032343
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:52:34

FDA-CBER-2022-1614-0175208

US3032343
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:52:34

FDA-CBER-2022-1614-0175209

US3032343
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:52:34

FDA-CBER-2022-1614-0175210

US3032343
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:52:34

FDA-CBER-2022-1614-0175211

US3032343
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	30 Mar 2021 15:52:34

FDA-CBER-2022-1614-0175212

US3032343
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:52:34

FDA-CBER-2022-1614-0175213

US3032343
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	30 Mar 2021 15:52:34

FDA-CBER-2022-1614-0175214

US3032343
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:52:34

FDA-CBER-2022-1614-0175215

US3032343
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	30 Mar 2021 15:52:34

FDA-CBER-2022-1614-0175216

US3032343
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:52:34

FDA-CBER-2022-1614-0175217

US3032343
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	30 Mar 2021 15:52:34

FDA-CBER-2022-1614-0175218

US3032343
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25

FDA-CBER-2022-1614-0175219

US3032343
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25

FDA-CBER-2022-1614-0175220

US3032343
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:56:17
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:53:10

FDA-CBER-2022-1614-0175221

US3032343
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:56:17
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:53:10

FDA-CBER-2022-1614-0175222

US3032343
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:56:17
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:53:12

FDA-CBER-2022-1614-0175223

US3032343
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:56:17
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:53:12

FDA-CBER-2022-1614-0175224

US3032343
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:56:17
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:53:12

FDA-CBER-2022-1614-0175225

US3032343
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:56:17
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	30 Mar 2021 15:53:12

FDA-CBER-2022-1614-0175226

US3032343
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:53:49
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:53:15

FDA-CBER-2022-1614-0175227

US3032343
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:56:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	30 Mar 2021 15:53:49
User entered '1'	System	30 Mar 2021 15:53:15

FDA-CBER-2022-1614-0175228

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 21:56:17
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User accepted default value 'Day 3 (Day 3)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

FDA-CBER-2022-1614-0175229

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 21:56:17
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

FDA-CBER-2022-1614-0175230

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 21:56:17
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

FDA-CBER-2022-1614-0175231

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 21:56:17
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User accepted default value 'Day 5 (Day 5)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

FDA-CBER-2022-1614-0175232

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 21:56:17
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

FDA-CBER-2022-1614-0175233

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 21:56:17
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

FDA-CBER-2022-1614-0175234

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 21:56:17
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User accepted default value 'Day 7 (Day 7)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

FDA-CBER-2022-1614-0175235

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 21:56:17
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

FDA-CBER-2022-1614-0175236

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 21:56:17
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

FDA-CBER-2022-1614-0175237

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 21:56:17
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User accepted default value 'Day 9 (Day 9)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

FDA-CBER-2022-1614-0175238

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 21:56:17
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

FDA-CBER-2022-1614-0175239

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 21:56:17
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

FDA-CBER-2022-1614-0175240

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 21:56:17
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User accepted default value 'Day 14 (Day 14)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

FDA-CBER-2022-1614-0175241

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 21:56:17
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

FDA-CBER-2022-1614-0175242

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 21:56:17
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

FDA-CBER-2022-1614-0175243

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 21:56:17
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User accepted default value 'Day 21 (Day 21)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

FDA-CBER-2022-1614-0175244

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 21:56:17
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

FDA-CBER-2022-1614-0175245

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 21:56:17
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

FDA-CBER-2022-1614-0175246

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 21:56:17
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User accepted default value 'Day 28 (Day 28)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

FDA-CBER-2022-1614-0175247

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 21:56:17
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

US3032343
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 21:56:17
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:29

FDA-CBER-2022-1614-0175249

US3032343
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:42

FDA-CBER-2022-1614-0175250

US3032343
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '30 Mar 2021'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:42

FDA-CBER-2022-1614-0175251

US3032343
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:42

FDA-CBER-2022-1614-0175252

US3032343
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'SICKD1'	System	30 Mar 2021 15:54:42

FDA-CBER-2022-1614-0175253

US3032343
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:48

FDA-CBER-2022-1614-0175254

US3032343
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:48

FDA-CBER-2022-1614-0175255

US3032343
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:48

FDA-CBER-2022-1614-0175256

US3032343
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	30 Mar 2021 15:54:48

FDA-CBER-2022-1614-0175257

US3032343
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:48
DataPoint set to visible.	System	30 Mar 2021 15:54:42

FDA-CBER-2022-1614-0175258

US3032343
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:48
DataPoint set to visible.	System	30 Mar 2021 15:54:42

FDA-CBER-2022-1614-0175259

US3032343
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:48

FDA-CBER-2022-1614-0175260

US3032343
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:48

FDA-CBER-2022-1614-0175261

US3032343
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:48

FDA-CBER-2022-1614-0175262

US3032343
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:48

FDA-CBER-2022-1614-0175263

US3032343
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	30 Mar 2021 15:54:48

FDA-CBER-2022-1614-0175264

US3032343
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:48

US3032343
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	30 Mar 2021 15:54:48

FDA-CBER-2022-1614-0175266

US3032343
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:48

FDA-CBER-2022-1614-0175267

US3032343
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	30 Mar 2021 15:54:48

FDA-CBER-2022-1614-0175268

US3032343
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:48

FDA-CBER-2022-1614-0175269

US3032343
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	30 Mar 2021 15:54:48

FDA-CBER-2022-1614-0175270

US3032343
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25

FDA-CBER-2022-1614-0175271

US3032343
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25

FDA-CBER-2022-1614-0175272

US3032343
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:56:17
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:55

FDA-CBER-2022-1614-0175273

US3032343
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:56:17
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:55

FDA-CBER-2022-1614-0175274

US3032343
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 21:56:17
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:55:00

US3032343
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 21:56:17
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:55:00

FDA-CBER-2022-1614-0175276

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:11

FDA-CBER-2022-1614-0175277

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:11

FDA-CBER-2022-1614-0175278

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:11

FDA-CBER-2022-1614-0175279

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'SICKD28'	System	30 Mar 2021 15:54:11

FDA-CBER-2022-1614-0175280

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:14

FDA-CBER-2022-1614-0175281

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:14

FDA-CBER-2022-1614-0175282

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:14

FDA-CBER-2022-1614-0175283

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	30 Mar 2021 15:54:14

FDA-CBER-2022-1614-0175284

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:14

FDA-CBER-2022-1614-0175285

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:14

FDA-CBER-2022-1614-0175286

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:14

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:14

FDA-CBER-2022-1614-0175288

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	30 Mar 2021 15:54:14

FDA-CBER-2022-1614-0175289

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:14

FDA-CBER-2022-1614-0175290

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	30 Mar 2021 15:54:14

FDA-CBER-2022-1614-0175291

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:14

FDA-CBER-2022-1614-0175292

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	30 Mar 2021 15:54:14

FDA-CBER-2022-1614-0175293

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:14

FDA-CBER-2022-1614-0175294

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	30 Mar 2021 15:54:14

FDA-CBER-2022-1614-0175295

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25

FDA-CBER-2022-1614-0175296

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:56:17
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25

FDA-CBER-2022-1614-0175297

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:56:17
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:16

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:56:17
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:16

FDA-CBER-2022-1614-0175299

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 21:56:17
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:20

US3032343
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 21:56:17
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:54:20

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	22 Mar 2021 20:38:14

FDA-CBER-2022-1614-0175302

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '23 Feb 2021'	Kelsey Kelley (b) (4) (b) (4)	22 Mar 2021 20:38:14

FDA-CBER-2022-1614-0175303

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4) (b) (4)	22 Mar 2021 20:38:14

FDA-CBER-2022-1614-0175304

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:56:17
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered 'UNBLND_DECIDE'	System	22 Mar 2021 20:38:14

FDA-CBER-2022-1614-0175305

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 21:56:17
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '23 Feb 2021'	Kelsey Kelley (b) (4) (b) (4)	22 Mar 2021 20:38:45

FDA-CBER-2022-1614-0175306

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 21:56:17
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	22 Mar 2021 20:38:45

FDA-CBER-2022-1614-0175307

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 21:56:17
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	22 Mar 2021 20:38:45

FDA-CBER-2022-1614-0175308

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 21:56:17
Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Amendment 6 or later (Amendment 6 or later)'	Kelsey Kelley (b) (4) (b) (4)	22 Mar 2021 20:38:45

FDA-CBER-2022-1614-0175309

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 21:56:17
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '23 Feb 2021'	Kelsey Kelley (b) (4) (b) (4)	22 Mar 2021 20:38:45

FDA-CBER-2022-1614-0175310

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 21:56:17
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'mRNA-1273 (mRNA-1273)'	Kelsey Kelley (b) (4) (b) (4)	22 Mar 2021 20:38:45

FDA-CBER-2022-1614-0175311

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 21:56:17
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'mRNA-1273 (mRNA-1273)'	Kelsey Kelley (b) (4) (b) (4)	22 Mar 2021 20:38:45

FDA-CBER-2022-1614-0175312

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 21:56:17
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'mRNA-1273 (mRNA-1273)'	Kelsey Kelley (b) (4) (b) (4)	22 Mar 2021 20:38:45

FDA-CBER-2022-1614-0175313

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 21:56:17
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	22 Mar 2021 20:38:45

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 21:56:17
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	22 Mar 2021 20:38:45

FDA-CBER-2022-1614-0175315

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 21:56:17
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	22 Mar 2021 20:38:45

FDA-CBER-2022-1614-0175316

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:56:17
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	22 Mar 2021 20:39:05

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:56:17
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '23 Feb 2021'	Kelsey Kelley (b) (4) (b) (4)	22 Mar 2021 20:39:05

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:56:17
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '09:30'	Kelsey Kelley (b) (4) (b) (4)	22 Mar 2021 20:39:05

FDA-CBER-2022-1614-0175319

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:56:17
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '23 Feb 2021 09:30'	System	22 Mar 2021 20:39:05

FDA-CBER-2022-1614-0175320

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 11 Aug 2021 21:56:17
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	22 Mar 2021 20:39:17

FDA-CBER-2022-1614-0175321

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 11 Aug 2021 21:56:17
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '23 Feb 2021'	Kelsey Kelley (b) (4) (b) (4)	22 Mar 2021 20:39:17

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 11 Aug 2021 21:56:17
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '09:37'	Kelsey Kelley (b) (4) (b) (4)	22 Mar 2021 20:39:17

FDA-CBER-2022-1614-0175323

US3032343
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 11 Aug 2021 21:56:17
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '23 Feb 2021 09:37'	System	22 Mar 2021 20:39:17

FDA-CBER-2022-1614-0175324

US3032343
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 11 Aug 2021 21:56:17
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:55:24
User entered 'Yes (Y)' reason for change: New Information	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:55:24
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	15 Sep 2020 22:47:05

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25

FDA-CBER-2022-1614-0175326

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4) (b) (4)	06 Apr 2021 15:47:44
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 15:58:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 15:58:07
Data point term sent to Coder	System	30 Mar 2021 15:56:38
User entered 'sore throat'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175327

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175328

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175329

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '24 Mar 2021'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175331

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175332

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175333

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175335

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175336

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175337

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175338

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175339

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175340

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175341

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175342

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175343

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175344

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175345

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175346

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175347

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175349

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Not Related (NOT RELATED)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175350

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Not Related (NOT RELATED)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175351

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175352

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175353

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '1'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175354

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175355

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175356

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175357

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175358

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '0'	System	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175359

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '1'	System	30 Mar 2021 15:56:13

FDA-CBER-2022-1614-0175360

US3032343
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:56:17
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25

FDA-CBER-2022-1614-0175361

US3032343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:56:17

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).		18 Feb 2021 13:40:09
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'subject took medication for injection site pain not underarm gland swelling' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	11 Feb 2021 22:53:08
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 07:30:18
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 21:26:14

US3032343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:56:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 21:28:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 21:28:48
Data point term sent to Coder	System	14 Sep 2020 21:27:17
User entered 'tylenol'	(b) (4), (b) (6)	14 Sep 2020 21:27:06

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:56:17
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 21:27:06

FDA-CBER-2022-1614-0175364

US3032343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:56:17

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).		22 Oct 2020 08:46:57
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' answered with 'PAIN AT INJECTION SITE did not meet the AE reporting criteria' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 17:36:10

US3032343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:56:17

Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 08:38:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:21:50
User entered 'pain at injection site'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 21:27:06

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:56:17
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:21:50
User entered '500'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 21:27:06

FDA-CBER-2022-1614-0175367

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:56:17
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:21:50
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 21:27:06

FDA-CBER-2022-1614-0175368

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:56:17
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:21:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 21:27:06

FDA-CBER-2022-1614-0175369

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:56:17
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:21:50
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 21:27:06

FDA-CBER-2022-1614-0175370

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:56:17
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:21:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 21:27:06

FDA-CBER-2022-1614-0175371

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:56:17
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:21:50
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 21:27:06

FDA-CBER-2022-1614-0175372

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:56:17
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:21:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 21:27:06

FDA-CBER-2022-1614-0175373

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:56:17
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:21:50
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 21:27:06

FDA-CBER-2022-1614-0175374

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:56:17
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:21:50
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 21:27:06

FDA-CBER-2022-1614-0175375

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:56:17
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 21:27:06

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:56:17
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:21:50
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 21:27:06

FDA-CBER-2022-1614-0175377

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:56:17
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:21:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 21:27:06

FDA-CBER-2022-1614-0175378

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:56:17
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	14 Sep 2020 21:27:06

FDA-CBER-2022-1614-0175379

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:56:17
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	14 Sep 2020 21:27:06

FDA-CBER-2022-1614-0175380

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 21:56:17
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered empty.	System	14 Sep 2020 21:27:06

FDA-CBER-2022-1614-0175381

US3032343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:56:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:47:44
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 15:59:40
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 Mar 2021 15:59:40
Data point term sent to Coder	System	30 Mar 2021 15:57:38
User entered 'amoxicillin'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:46

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:56:17
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:46

FDA-CBER-2022-1614-0175383

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:56:17
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'sore throat'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:46

FDA-CBER-2022-1614-0175384

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:56:17
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '500'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:46

FDA-CBER-2022-1614-0175385

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:56:17
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:46

FDA-CBER-2022-1614-0175386

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:56:17
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:46

FDA-CBER-2022-1614-0175387

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:56:17
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'three times daily (TID)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:46

FDA-CBER-2022-1614-0175388

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:56:17
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:46

FDA-CBER-2022-1614-0175389

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:56:17
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:46

FDA-CBER-2022-1614-0175390

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:56:17
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:46

FDA-CBER-2022-1614-0175391

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:56:17
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '24 Mar 2021'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:46

FDA-CBER-2022-1614-0175392

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:56:17
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:46

FDA-CBER-2022-1614-0175393

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:56:17
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:46

FDA-CBER-2022-1614-0175394

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:56:17
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:46

FDA-CBER-2022-1614-0175395

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:56:17
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:56:46

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:56:17
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '3'	System	30 Mar 2021 15:56:46

FDA-CBER-2022-1614-0175397

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:56:17
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '1'	System	30 Mar 2021 15:56:46

FDA-CBER-2022-1614-0175398

US3032343
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 21:56:17
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User entered '804 (804)'	System	30 Mar 2021 15:56:46

FDA-CBER-2022-1614-0175399

US3032343
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 11 Aug 2021 21:56:17
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:21:50
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	15 Sep 2020 22:47:12

US3032343
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 21:56:17
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:59:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered '30 Mar 2021'	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 14:43:56

FDA-CBER-2022-1614-0175401

US3032343
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 21:56:17
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:59:20
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).		28 Apr 2021 06:21:01
Query 'Per CDM : Per CCGs, relocation should be listed other OTHER as reason for discontinuation. Please verify and amend. Thank you ' answered with 'subject chose to WITHDRAW consent due to relocation. ' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	19 Apr 2021 13:58:30
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 07:26:32
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 14:43:56

FDA-CBER-2022-1614-0175402

US3032343

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:56:17

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)	29 Apr 2021 04:59:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered 'Subject is moving out of state and can not make the rest of her visits. She decided to withdraw consent.'	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 14:43:56

US3032343
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 21:56:17
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:59:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 14:43:56

FDA-CBER-2022-1614-0175404

US3032343
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 21:56:17
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:59:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 14:43:56

FDA-CBER-2022-1614-0175405

US3032343
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 21:56:17
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:59:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 14:43:56

FDA-CBER-2022-1614-0175406

US3032343
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 21:56:17
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:59:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:47:44
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 14:43:56

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