US3382085 (Prod: Advanced Clinical Research – Be Well MD - ERN - PPDS)

Generated By: KC Joubran

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US3382085
Form: Participant Creation
Data signed: (b) (4) **26 Jan 2021 19:10:51**
Generated On: 09 Jun 2021 17:19:35

Participant ID	US3382085

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-0110198

US3382085
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-0110199

US3382085
Folder: Screening
Form: Demographics
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

Date of Birth (MMM yyyy)	(b) (6) 1978
Age	41
Age Units	YEARS
Age (Derived)	41
Sex	Female ■ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ■ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

FDA-CBER-2022-1614-0110200

US3382085
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

Date of Informed Consent *(dd MMM yyyy)*	20 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐ Amendment 2 ■ Amendment 3 ☐ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ■ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ■
If Yes, previous participant number	
Enrollment Trigger	1

FDA-CBER-2022-1614-0110201

US3382085
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

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

FDA-CBER-2022-1614-0110202

US3382085
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-0110203

US3382085
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

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

FDA-CBER-2022-1614-0110204

US3382085
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

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

FDA-CBER-2022-1614-0110205

US3382085
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

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

FDA-CBER-2022-1614-0110206

US3382085
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

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

FDA-CBER-2022-1614-0110207

US3382085
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

Condition	CHOLELITHIASIS
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

US3382085
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

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

US3382085
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

US3382085
Folder: Screening
Form: Medical History (8)
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

Condition	MENISCAL LOOSE BODY - LEFT KNEE
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992

FDA-CBER-2022-1614-0110211

US3382085
Folder: Screening
Form: Medical History (9)
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

Condition	LEFT KNEE SCOPE WITH MENISCAL LOOSE BODY REMOVAL
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992

FDA-CBER-2022-1614-0110212

US3382085
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	20 AUG 2020
Time of assessment *(00:00-23:59)*	14:26 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 14:26
Height *(xxx.x)*	64 in
Weight *(xxx.x)*	227.3 lb
BMI *(xxx.x)*	39.09753 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-2022-1614-0110213

US3382085
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **26 Jan 2021 19:10:52**
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Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	20 AUG 2020

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

FDA-CBER-2022-1614-0110214

US3382085
Folder: Screening
Form: Childbearing Potential
Data signed: (b) (4) **26 Jan 2021 19:10:52**
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Date of assessment *(dd MMM yyyy)*	20 AUG 2020
Is the participant of childbearing potential?	Yes ■ No ☐
If No, what is the reason?	Surgically sterile ☐ Post-menopausal ☐ Partner medically sterile ☐ Not reached age of Menarche ☐ Other ☐
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	False

FDA-CBER-2022-1614-0110215

US3382085
Folder: Screening
Form: Pregnancy Test
Data signed: (b) (4) **26 Jan 2021 19:10:52**
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Was the pregnancy test performed?	Yes ■ No ☐
Date of test *(dd MMM yyyy)*	20 AUG 2020
Test performed	Urine ■ Serum ☐
Result	Positive ☐ Negative ■
Was FSH sample collected?	Yes ☐ No ■
Collection date	
Collection time	
Collection date and time (derived)	

FDA-CBER-2022-1614-0110216

US3382085
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **26 Jan 2021 19:10:52**
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Occupational Risk	
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☐ No ■
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐ No ■
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐ No ■
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐ No ■
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐ No ■
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐ No ■
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐ No ■
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐ No ■
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐ No ■
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐ No ■
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐ No ■
Other	Yes ■ No ☐
Specify	PROJECT MANAGER-CLINICAL RESEARCH

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

US3382085
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **26 Jan 2021 19:10:52**
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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

FDA-CBER-2022-1614-0110218

US3382085
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **26 Jan 2021 19:10:53**
Generated On: 09 Jun 2021 17:19:35

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-0110219

US3382085
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **26 Jan 2021 19:10:53**
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What was the date of randomization? *(dd MMM yyyy)*	20 AUG 2020
What was the participant's randomization number?	106414
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-2022-1614-0110220

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **26 Jan 2021 19:10:53**
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Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-0110221

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **26 Jan 2021 19:10:53**
Generated On: 09 Jun 2021 17:19:35

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)*	20 AUG 2020
Time of assessment *(00:00-23:59)*	14:26 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 14:26
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	72 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	81 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0110222

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **26 Jan 2021 19:10:53**
Generated On: 09 Jun 2021 17:19:35

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)*	20 AUG 2020
Time of assessment *(00:00-23:59)*	15:36 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 15:36
Temperature *(xxx.x)*	97.3 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	89 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0110223

US3382085
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

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

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

FDA-CBER-2022-1614-0110224

US3382085
Folder: Visit 1 Day 1
Form: Pregnancy Test
Data signed: (b) (4) **26 Jan 2021 19:10:52**
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Was the pregnancy test performed?	Yes ☐ No ■
Date of test *(dd MMM yyyy)*	
Test performed	Urine ☐ Serum ☐
Result	Positive ☐ Negative ☐
Was FSH sample collected?	Yes ☐ No ☐
Collection date	
Collection time	
Collection date and time (derived)	

FDA-CBER-2022-1614-0110225

US3382085
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **26 Jan 2021 19:10:52**
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Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	20 AUG 2020
What was the treatment time? *(00:00-23:59)*	15:00 (24 HR)
Treatment Date and Time (derived)	20 AUG 2020 15:00
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-2022-1614-0110226

US3382085
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **26 Jan 2021 19:10:52**
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Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	20 AUG 2020
Collection time *(00:00-23:59)*	13:58 (24 HR)
Collection date and time (derived)	20 AUG 2020 13:58

FDA-CBER-2022-1614-0110227

US3382085
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

Collection date *(dd MMM yyyy)*			20 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:57	20 AUG 2020 13:57
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0110228

US3382085
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **26 Jan 2021 19:10:52**
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Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0110229

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	20 AUG 2020 15:54
PC Open Date & Time	20 AUG 2020 15:20
PC Close Date & Time	20 AUG 2020 17:50

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**	98.1 °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	20 AUG 2020 20:11
PC Open Date & Time	20 AUG 2020 18:45
PC Close Date & Time	21 AUG 2020 11:59

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:19:35

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	98.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	22 AUG 2020 00:57
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:19:35

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.9 °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	22 AUG 2020 23:14
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:19:35

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**	98.5 °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	23 AUG 2020 20:03
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:19:35

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.8 °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	24 AUG 2020 23:59
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:19:35

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**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	25 AUG 2020 23:01
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:19:35

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	26 AUG 2020 23:12
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:19:35

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	20 AUG 2020 15:20
PC Close Date & Time	20 AUG 2020 17:50

FDA-CBER-2022-1614-0110238

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:19:35

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 - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	4
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	20 AUG 2020 20:49
PC Open Date & Time	20 AUG 2020 18:45
PC Close Date & Time	21 AUG 2020 11:59

FDA-CBER-2022-1614-0110239

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:19:35

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 - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	2
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	22 AUG 2020 00:58
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:19:35

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

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:19:35

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	23 AUG 2020 20:02
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-0110242

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:19:35

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	24 AUG 2020 23:58
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:19:35

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	25 AUG 2020 23:00
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:19:35

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	26 AUG 2020 23:11
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

FDA-CBER-2022-1614-0110245

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 ☐

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:19:35

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	20 AUG 2020 15:20
PC Close Date & Time	20 AUG 2020 17:50

FDA-CBER-2022-1614-0110247

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 ☐

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:19:35

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	20 AUG 2020 20:54
PC Open Date & Time	20 AUG 2020 18:45
PC Close Date & Time	21 AUG 2020 11:59

FDA-CBER-2022-1614-0110249

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:19:35

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-2022-1614-0110250

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:19:35

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

FDA-CBER-2022-1614-0110251

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 ■

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:19:35

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

FDA-CBER-2022-1614-0110253

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 ■

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:19:35

	Yes ☐
PC Time stamp	23 AUG 2020 20:03
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-0110255

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 ■

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:19:35

	Yes ☐
PC Time stamp	24 AUG 2020 23:58
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-0110257

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:19:35

TIMEPOINT	DAY 6
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-0110258

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:19:35

	Yes ☐
PC Time stamp	25 AUG 2020 23:01
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:19:35

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

FDA-CBER-2022-1614-0110260

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:19:35

	Yes ☐
PC Time stamp	26 AUG 2020 23:11
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

FDA-CBER-2022-1614-0110261

US3382085
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	27 AUG 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0110262

US3382085
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

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

FDA-CBER-2022-1614-0110263

US3382085
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	03 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-2022-1614-0110264

US3382085
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

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

FDA-CBER-2022-1614-0110265

US3382085
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	10 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-2022-1614-0110266

US3382085
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

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

FDA-CBER-2022-1614-0110267

US3382085
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **26 Jan 2021 19:10:53**
Generated On: 09 Jun 2021 17:19:35

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	25 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-0110268

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **26 Jan 2021 19:10:53**
Generated On: 09 Jun 2021 17:19:35

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	25 SEP 2020
Time of assessment *(00:00-23:59)*	11:32 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 11:32
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	79 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	71 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0110269

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **26 Jan 2021 19:10:53**
Generated On: 09 Jun 2021 17:19:35

Timepoint	Pre-Dose ☐ Post-Dose ■
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	

FDA-CBER-2022-1614-0110270

US3382085
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **26 Jan 2021 19:10:53**
Generated On: 09 Jun 2021 17:19:35

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.

US3382085
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Data signed: (b) (4) **26 Jan 2021 19:10:53**
Generated On: 09 Jun 2021 17:19:35

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-2022-1614-0110272

US3382085
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **26 Jan 2021 19:10:53**
Generated On: 09 Jun 2021 17:19:35

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	PI WANTS TO WAIT UNTIL RASH HAS RESOLVED UNTIL ADMINISTERING MEDICATION; VISIT HAS BEEN RESCHEDULED
What was the study treatment?	
What was the treatment date? *(dd MMM yyyy)*	
What was the treatment time? *(00:00-23:59)*	
Treatment Date and Time (derived)	
Which arm was used to give treatment?	Left Arm ☐ Right Arm ☐
What was the frequency of the study treatment dosing?	
What was the route of administration for the study treatment?	

FDA-CBER-2022-1614-0110273

US3382085
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **26 Jan 2021 19:10:53**
Generated On: 09 Jun 2021 17:19:35

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

US3382085
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **26 Jan 2021 19:10:53**
Generated On: 09 Jun 2021 17:19:35

Collection date *(dd MMM yyyy)*

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0110275

US3382085
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **26 Jan 2021 19:10:53**
Generated On: 09 Jun 2021 17:19:35

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

FDA-CBER-2022-1614-0110276

US3382085
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **30 Mar 2021 13:48:46**
Generated On: 09 Jun 2021 17:19:35

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

FDA-CBER-2022-1614-0110277

US3382085
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **30 Mar 2021 13:48:46**
Generated On: 09 Jun 2021 17:19:35

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

FDA-CBER-2022-1614-0110278

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

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3382085
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 09 Jun 2021 17:19:35

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

FDA-CBER-2022-1614-0110287

US3382085
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 17:19:35

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-2022-1614-0110288

US3382085
Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Generated On: 09 Jun 2021 17:19:35

Generate Next COVID-19 Assessment	Yes ☐ No ☐

FDA-CBER-2022-1614-0110289

US3382085
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:19:35

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

FDA-CBER-2022-1614-0110290

US3382085
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:19:35

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

FDA-CBER-2022-1614-0110291

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

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

US3382085
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **26 Jan 2021 19:10:51**
Generated On: 09 Jun 2021 17:19:35

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

If Yes, enter details on the Adverse Events form.

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **26 Jan 2021 19:10:51**
Generated On: 09 Jun 2021 17:19:35

AEID	
Adverse event	ALLERGIC RASH - UNKNOWN ETIOLOGY
Was this a medically-attended AE?	Yes ■ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ■
Start date *(dd MMM yyyy)*	12 SEP 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ■ No ☐
If not Ongoing, end date *(dd MMM yyyy)*	
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ■ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	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)	

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

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

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

FDA-CBER-2022-1614-0110297

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **26 Jan 2021 19:10:51**
Generated On: 09 Jun 2021 17:19:35

Name of Medication	LESSINA
Prophylaxis	Yes ■ No ☐
Indication	CONTRACEPTION
Dose per administration	0.1/20
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	MG/MCG
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 1999
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **26 Jan 2021 19:10:51**
Generated On: 09 Jun 2021 17:19:35

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2014
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **26 Jan 2021 19:10:51**
Generated On: 09 Jun 2021 17:19:35

Name of Medication	LAMICTAL
Prophylaxis	Yes ☐ No ■
Indication	DEPRESSION
Dose per administration	300
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2014
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **26 Jan 2021 19:10:51**
Generated On: 09 Jun 2021 17:19:35

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

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	Intramuscular ☐ Respiratory (Inhalation) ☐ Intralesional ☐ Intraperiteoneal ☐ Nasal ☐ Vaginal ☐ Rectal ☐ Intravenous ☐ Intravenous Bolus ☐ Intravenous Drip ☐ Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2000
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	08 SEP 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **26 Jan 2021 19:10:51**
Generated On: 09 Jun 2021 17:19:35

Name of Medication	BENADRYL
Prophylaxis	Yes No ■
Indication	ALLERGIC RASH - UNKNOWN ETIOLOGY
Dose per administration	25
Dose unit	mg ■ ug mL g IU tablet capsule puff Other
If dose unit is Other, specify	
Frequency	once daily ■ twice daily three times daily four times daily every other day every week every month as needed once unknown other
If frequency is Other, specify	
Route of administration	Oral ■ Topical Subcutaneous Transdermal

	Intraocular ☐
	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)*	13 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	14 SEP 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **26 Jan 2021 19:10:51**
Generated On: 09 Jun 2021 17:19:35

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

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	15 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	22 SEP 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **26 Jan 2021 19:10:51**
Generated On: 09 Jun 2021 17:19:35

Name of Medication	METHYLPREDNISOLONE
Prophylaxis	Yes ☐ No ■
Indication	ALLERGIC REACTION - UNKNOWN ETIOLOGY
Dose per administration	24
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)*	15 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	15 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 ☐

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **26 Jan 2021 19:10:51**
Generated On: 09 Jun 2021 17:19:35

Name of Medication	METHYLPREDNISOLONE
Prophylaxis	Yes ☐ No ■
Indication	ALLERGIC REACTION - UNKNOWN ETIOLOGY
Dose per administration	20
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	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)*	16 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	16 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 ☐

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **26 Jan 2021 19:10:51**
Generated On: 09 Jun 2021 17:19:35

Name of Medication	METHYLPREDNISOLONE
Prophylaxis	Yes ☐ No ■
Indication	ALLERGIC REACTION - UNKNOWN ETIOLOGY
Dose per administration	16
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

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	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	17 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 ☐

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **26 Jan 2021 19:10:51**
Generated On: 09 Jun 2021 17:19:35

Name of Medication	METHYLPREDNISOLONE
Prophylaxis	Yes No ■
Indication	ALLERGIC REACTION - UNKNOWN ETIOLOGY
Dose per administration	12
Dose unit	mg ■ ug mL g IU tablet capsule puff Other
If dose unit is Other, specify	
Frequency	once daily twice daily three times daily four times daily every other day every week every month as needed once ■ unknown other
If frequency is Other, specify	
Route of administration	Oral ■ Topical Subcutaneous Transdermal

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	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	18 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	18 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 ☐

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Data signed: (b) (4) **26 Jan 2021 19:10:51**
Generated On: 09 Jun 2021 17:19:35

Name of Medication	METHYLPREDNISOLONE
Prophylaxis	Yes No ■
Indication	ALLERGIC REACTION - UNKNOWN ETIOLOGY
Dose per administration	8
Dose unit	mg ■ ug mL g IU tablet capsule puff Other
If dose unit is Other, specify	
Frequency	once daily twice daily three times daily four times daily every other day every week every month as needed once ■ unknown other
If frequency is Other, specify	
Route of administration	Oral ■ Topical Subcutaneous Transdermal

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	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	19 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	19 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 ☐

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Data signed: (b) (4) **26 Jan 2021 19:10:51**
Generated On: 09 Jun 2021 17:19:35

Name of Medication	ZYRTEC-(CETIRIZINE)
Prophylaxis	Yes ☐ No ■
Indication	ALLERGIC REACTION - UNKNOWN ETIOLOGY
Dose per administration	20
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	15 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	20 SEP 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Data signed: (b) (4) **26 Jan 2021 19:10:51**
Generated On: 09 Jun 2021 17:19:35

Name of Medication	METHYLPREDNISOLONE
Prophylaxis	Yes ☐ No ■
Indication	ALLERGIC DERMATITIS OF UNKNOWN ETIOLOGY
Dose per administration	4
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
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)*	20 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	20 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 ☐

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Data signed: (b) (4) **26 Jan 2021 19:10:51**
Generated On: 09 Jun 2021 17:19:35

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

US3382085
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

Were any concomitant procedures performed?	Yes ☐ No ☒

If yes, please complete Concomitant Procedures form.

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US3382085
Folder: End of Study (1)
Form: Dosing Discontinuation
Data signed: (b) (4) **26 Jan 2021 19:10:52**
Generated On: 09 Jun 2021 17:19:35

Date of dosing discontinuation (dd MMM yyyy)	25 SEP 2020
Primary reason for dosing discontinuation	AE (specify) ■ SAE (specify) ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Due to SARS-COV-2 ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	AE #1

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US3382085
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **28 Apr 2021 03:22:02**
Generated On: 09 Jun 2021 17:19:35

Date of study discontinuation/completion *(dd MMM yyyy)*	25 SEP 2020
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	AE #1
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 ☐

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US3382085
Form: Participant Creation
Generated On: 09 Jun 2021 17:19:35
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'US3382085'	RWS_ENDPOINT ENDPOINT(b) (4)	20 Aug 2020 17:45:11

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US3382085
Form: Participant Creation
Generated On: 09 Jun 2021 17:19:35

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

FDA-CBER-2022-1614-0110331

US3382085
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:19:35
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:51:20

FDA-CBER-2022-1614-0110332

US3382085
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:19:35
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT(b) (4)	20 Aug 2020 17:45:12

FDA-CBER-2022-1614-0110333

US3382085
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:19:35
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Aug 2020 20:51:20

FDA-CBER-2022-1614-0110334

US3382085
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:19:35
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'SCRN'	System	20 Aug 2020 20:51:20

FDA-CBER-2022-1614-0110335

US3382085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:19:35
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '(b) (6) 1978'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 17:45:13

FDA-CBER-2022-1614-0110336

US3382085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:19:35
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '41'	(b) (4), (b) (6)	25 Aug 2020 18:06:00

FDA-CBER-2022-1614-0110337

US3382085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:19:35
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'YEARS'	System	25 Aug 2020 18:06:00

FDA-CBER-2022-1614-0110338

US3382085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:19:35
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered '41'	System	20 Aug 2020 20:52:19

FDA-CBER-2022-1614-0110339

US3382085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:19:35
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Female (F)'	(b) (4), (b) (6)	25 Aug 2020 18:06:00

FDA-CBER-2022-1614-0110340

US3382085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:19:35
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 19:10:53
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:06:00

FDA-CBER-2022-1614-0110341

US3382085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:19:35
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '1'	(b) (4), (b) (6)	25 Aug 2020 18:06:00

FDA-CBER-2022-1614-0110342

US3382085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:19:35
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:06:00

FDA-CBER-2022-1614-0110343

US3382085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:19:35
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:06:00

FDA-CBER-2022-1614-0110344

US3382085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:19:35
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:06:00

FDA-CBER-2022-1614-0110345

US3382085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:19:35
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:06:00

FDA-CBER-2022-1614-0110346

US3382085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:19:35
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:06:00

FDA-CBER-2022-1614-0110347

US3382085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:19:35
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:06:00

FDA-CBER-2022-1614-0110348

US3382085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:19:35
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:06:00

FDA-CBER-2022-1614-0110349

US3382085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:19:35
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:06:00

FDA-CBER-2022-1614-0110350

US3382085
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:19:35
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 20:52:19

FDA-CBER-2022-1614-0110351

US3382085
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:19:35
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'Aug 2020'	System	20 Aug 2020 20:52:19

FDA-CBER-2022-1614-0110352

US3382085
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:19:35
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered '2020'	System	20 Aug 2020 20:52:19

FDA-CBER-2022-1614-0110353

US3382085
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:19:35
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 19:10:53
User entered 'Amendment 2 (2)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:52:19

FDA-CBER-2022-1614-0110354

US3382085
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:19:35
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:52:19

FDA-CBER-2022-1614-0110355

US3382085
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:19:35
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:52:19

FDA-CBER-2022-1614-0110356

US3382085
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:19:35
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:52:19

FDA-CBER-2022-1614-0110357

US3382085
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:19:35
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:52:19

FDA-CBER-2022-1614-0110358

US3382085
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:19:35
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	RWS_ENDPOINT ENDPOINT(b) (4)	20 Aug 2020 17:45:12

FDA-CBER-2022-1614-0110359

US3382085
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:19:35
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered '1'	System	20 Aug 2020 20:52:19

FDA-CBER-2022-1614-0110360

US3382085
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 09 Jun 2021 17:19:35
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:51:37

FDA-CBER-2022-1614-0110361

US3382085
Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 17:19:35
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:26:59

FDA-CBER-2022-1614-0110362

US3382085
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:19:35
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 13:28:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 13:28:46
Data point term sent to Coder	System	22 Sep 2020 13:27:59
User entered 'Depression'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:27:28

FDA-CBER-2022-1614-0110363

US3382085
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:19:35
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'UN UNK 2014'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:27:28

FDA-CBER-2022-1614-0110364

US3382085
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:27:28

US3382085
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:19:35
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:27:28

FDA-CBER-2022-1614-0110366

US3382085
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:19:35
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:27:28

FDA-CBER-2022-1614-0110367

US3382085
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:19:35
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:27:28

FDA-CBER-2022-1614-0110368

US3382085
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:19:35
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'Jan 2014'	System	22 Sep 2020 13:27:28

FDA-CBER-2022-1614-0110369

US3382085
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:19:35
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered '2014'	System	22 Sep 2020 13:27:28

FDA-CBER-2022-1614-0110370

US3382085
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:19:35
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered empty.	System	22 Sep 2020 13:27:28

FDA-CBER-2022-1614-0110371

US3382085
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:19:35
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered empty.	System	22 Sep 2020 13:27:28

FDA-CBER-2022-1614-0110372

US3382085
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:19:35
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 13:29:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 13:29:36
Data point term sent to Coder	System	22 Sep 2020 13:28:59
User entered 'Anxiety'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:28:01

FDA-CBER-2022-1614-0110373

US3382085
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:19:35
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'UN UNK 2014'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:28:01

FDA-CBER-2022-1614-0110374

US3382085
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:28:01

US3382085
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:19:35
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:28:01

FDA-CBER-2022-1614-0110376

US3382085
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:19:35
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:28:01

FDA-CBER-2022-1614-0110377

US3382085
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:19:35
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:28:01

FDA-CBER-2022-1614-0110378

US3382085
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:19:35
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'Jan 2014'	System	22 Sep 2020 13:28:01

FDA-CBER-2022-1614-0110379

US3382085
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:19:35
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered '2014'	System	22 Sep 2020 13:28:01

FDA-CBER-2022-1614-0110380

US3382085
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:19:35
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered empty.	System	22 Sep 2020 13:28:01

FDA-CBER-2022-1614-0110381

US3382085
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:19:35
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered empty.	System	22 Sep 2020 13:28:01

FDA-CBER-2022-1614-0110382

US3382085
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:19:35
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 13:29:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 13:29:36
Data point term sent to Coder	System	22 Sep 2020 13:29:00
User entered 'Seasonal Allergies'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:29:00

FDA-CBER-2022-1614-0110383

US3382085
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:19:35
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'UN UNK 2000'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:29:00

FDA-CBER-2022-1614-0110384

US3382085
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:29:00

US3382085
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:19:35
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:29:00

FDA-CBER-2022-1614-0110386

US3382085
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:19:35
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:29:00

FDA-CBER-2022-1614-0110387

US3382085
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:19:35
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:29:00

FDA-CBER-2022-1614-0110388

US3382085
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:19:35
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'Jan 2000'	System	22 Sep 2020 13:29:00

FDA-CBER-2022-1614-0110389

US3382085
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:19:35
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered '2000'	System	22 Sep 2020 13:29:00

FDA-CBER-2022-1614-0110390

US3382085
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:19:35
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered empty.	System	22 Sep 2020 13:29:00

FDA-CBER-2022-1614-0110391

US3382085
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:19:35
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered empty.	System	22 Sep 2020 13:29:00

FDA-CBER-2022-1614-0110392

US3382085
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:19:35
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Impor(b) (4) (b) (4)	22 Sep 2020 13:30:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Impor(b) (4) (b) (4)	22 Sep 2020 13:30:43
Data point term sent to Coder	System	22 Sep 2020 13:30:01
User entered 'Sulfa Allergy'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:29:43

FDA-CBER-2022-1614-0110393

US3382085
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:19:35
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'UN UNK 1985'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:29:43

FDA-CBER-2022-1614-0110394

US3382085
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:29:43

US3382085
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:19:35
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:29:43

FDA-CBER-2022-1614-0110396

US3382085
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:19:35
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:29:43

FDA-CBER-2022-1614-0110397

US3382085
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:19:35
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:29:43

FDA-CBER-2022-1614-0110398

US3382085
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:19:35
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'Jan 1985'	System	22 Sep 2020 13:29:43

FDA-CBER-2022-1614-0110399

US3382085
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:19:35
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered '1985'	System	22 Sep 2020 13:29:43

FDA-CBER-2022-1614-0110400

US3382085
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:19:35
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered empty.	System	22 Sep 2020 13:29:43

FDA-CBER-2022-1614-0110401

US3382085
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:19:35
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered empty.	System	22 Sep 2020 13:29:43

FDA-CBER-2022-1614-0110402

US3382085
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:19:35
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 13:32:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 13:32:37
Data point term sent to Coder	System	22 Sep 2020 13:32:05
User entered 'Cholelithiasis'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:31:28

FDA-CBER-2022-1614-0110403

US3382085
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:19:35
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'UN UNK 2013'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:31:28

FDA-CBER-2022-1614-0110404

US3382085
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:31:28

FDA-CBER-2022-1614-0110405

US3382085
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:19:35
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	01 Oct 2020 13:20:35
User entered 'No (N)' reason for change: Per Query Resolution	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:20:35
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	22 Sep 2020 13:31:28
User entered 'Yes (Y)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:31:28

FDA-CBER-2022-1614-0110406

US3382085
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:19:35
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'UN UNK 2013'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:31:28

FDA-CBER-2022-1614-0110407

US3382085
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:19:35
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:31:28

FDA-CBER-2022-1614-0110408

US3382085
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:19:35
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'Jan 2013'	System	22 Sep 2020 13:31:28

FDA-CBER-2022-1614-0110409

US3382085
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:19:35
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered '2013'	System	22 Sep 2020 13:31:28

FDA-CBER-2022-1614-0110410

US3382085
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:19:35
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'Jan 2013'	System	22 Sep 2020 13:31:28

FDA-CBER-2022-1614-0110411

US3382085
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:19:35
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered '2013'	System	22 Sep 2020 13:31:28

FDA-CBER-2022-1614-0110412

US3382085
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:19:35
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendicectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 13:38:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 13:38:52
Data point term sent to Coder	System	22 Sep 2020 13:37:15
User entered 'Appendectomy'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:36:18

FDA-CBER-2022-1614-0110413

US3382085
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:19:35
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'UN UNK 1994'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:36:18

FDA-CBER-2022-1614-0110414

US3382085
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:36:18

US3382085
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:19:35
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:36:18

FDA-CBER-2022-1614-0110416

US3382085
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:19:35
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'UN UNK 1994'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:36:18

FDA-CBER-2022-1614-0110417

US3382085
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:19:35
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:36:18

FDA-CBER-2022-1614-0110418

US3382085
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:19:35
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'Jan 1994'	System	22 Sep 2020 13:36:18

FDA-CBER-2022-1614-0110419

US3382085
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:19:35
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered '1994'	System	22 Sep 2020 13:36:18

FDA-CBER-2022-1614-0110420

US3382085
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:19:35
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'Jan 1994'	System	22 Sep 2020 13:36:18

FDA-CBER-2022-1614-0110421

US3382085
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:19:35
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered '1994'	System	22 Sep 2020 13:36:18

FDA-CBER-2022-1614-0110422

US3382085
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:19:35
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:19:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:19:50
Data point term sent to Coder	System	01 Oct 2020 13:18:53
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:17:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 13:17:53
User entered 'cholecystectomy' reason for change: Data Entry Error	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:17:53
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 13:56:04
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:56:04

FDA-CBER-2022-1614-0110423

US3382085
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:19:35
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	01 Oct 2020 13:17:53
User entered 'un UNK 2013' reason for change: Data Entry Error	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:17:53
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	22 Sep 2020 13:56:04
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:56:04

FDA-CBER-2022-1614-0110424

US3382085
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:56:04

US3382085
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:19:35
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:17:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 13:17:53
User entered 'No (N)' reason for change: Data Entry Error	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:17:53
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 13:56:04
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:56:04

FDA-CBER-2022-1614-0110426

US3382085
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:19:35
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'un UNK 2013' reason for change: Data Entry Error	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:17:53
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:56:04

FDA-CBER-2022-1614-0110427

US3382085
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:19:35
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:56:04

FDA-CBER-2022-1614-0110428

US3382085
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:19:35
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'Jan 2013'	System	01 Oct 2020 13:17:53
User entered empty.	System	22 Sep 2020 13:56:04

FDA-CBER-2022-1614-0110429

US3382085
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:19:35
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered '2013'	System	01 Oct 2020 13:17:53
User entered empty.	System	22 Sep 2020 13:56:04

FDA-CBER-2022-1614-0110430

US3382085
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:19:35
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'Jan 2013'	System	01 Oct 2020 13:17:53
User entered empty.	System	22 Sep 2020 13:56:04

FDA-CBER-2022-1614-0110431

US3382085
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:19:35
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered '2013'	System	01 Oct 2020 13:17:53
User entered empty.	System	22 Sep 2020 13:56:04

FDA-CBER-2022-1614-0110432

US3382085
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:19:35
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Loose body in joint, LLT: Loose body in knee - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 11:00:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 11:00:12
Data point term sent to Coder	System	01 Oct 2020 13:19:54
User entered 'meniscal loose body - left knee'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:19:05

FDA-CBER-2022-1614-0110433

US3382085
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:19:35
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'un UNK 1992'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:19:05

FDA-CBER-2022-1614-0110434

US3382085
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:19:05

FDA-CBER-2022-1614-0110435

US3382085
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:19:35
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:19:05

FDA-CBER-2022-1614-0110436

US3382085
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:19:35
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'un UNK 1992'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:19:05

FDA-CBER-2022-1614-0110437

US3382085
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:19:35
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:19:05

FDA-CBER-2022-1614-0110438

US3382085
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:19:35
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'Jan 1992'	System	01 Oct 2020 13:19:05

FDA-CBER-2022-1614-0110439

US3382085
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:19:35
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered '1992'	System	01 Oct 2020 13:19:05

FDA-CBER-2022-1614-0110440

US3382085
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:19:35
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'Jan 1992'	System	01 Oct 2020 13:19:05

FDA-CBER-2022-1614-0110441

US3382085
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:19:35
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered '1992'	System	01 Oct 2020 13:19:05

FDA-CBER-2022-1614-0110442

US3382085
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:19:35
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee operation, LLT: Knee operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:42:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:42:18
Data point term sent to Coder	System	01 Oct 2020 13:19:58
User entered 'left knee scope with meniscal loose body removal'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:19:30

FDA-CBER-2022-1614-0110443

US3382085
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:19:35
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'un UNK 1992'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:19:30

FDA-CBER-2022-1614-0110444

US3382085
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:19:30

US3382085
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:19:35
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:19:30

FDA-CBER-2022-1614-0110446

US3382085
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:19:35
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'un UNK 1992'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:19:30

FDA-CBER-2022-1614-0110447

US3382085
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:19:35
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:19:30

FDA-CBER-2022-1614-0110448

US3382085
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:19:35
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'Jan 1992'	System	01 Oct 2020 13:19:30

FDA-CBER-2022-1614-0110449

US3382085
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:19:35
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered '1992'	System	01 Oct 2020 13:19:30

FDA-CBER-2022-1614-0110450

US3382085
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:19:35
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'Jan 1992'	System	01 Oct 2020 13:19:30

FDA-CBER-2022-1614-0110451

US3382085
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:19:35
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered '1992'	System	01 Oct 2020 13:19:30

FDA-CBER-2022-1614-0110452

US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:58:00

FDA-CBER-2022-1614-0110453

US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '20 Aug 2020'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:58:00

FDA-CBER-2022-1614-0110454

US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '14:26'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:58:00

FDA-CBER-2022-1614-0110455

US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered '20 Aug 2020 14:26'	System	22 Sep 2020 13:58:00

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US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '64' in reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:28:20
User entered '61' in	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:58:00
DataPoint set to visible.	System	20 Aug 2020 20:52:19

US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Per CDM re-query: BMI is 43 kg/m2 but subject is not recorded as at risk. Please review and update or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:05:24
Query 'Per CDM re-query: BMI is 43 kg/m2 but subject is not recorded as at risk. Please review and update or clarify otherwise. Thank you!' answered with 'updated' (Site from DM).	Triny Cooper (b) (4)	06 Oct 2020 17:49:34
User opened query 'Per CDM re-query: BMI is 43 kg/m2 but subject is not recorded as at risk. Please review and update or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 09:27:11
User entered '227.3' lb	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:58:00
DataPoint set to visible.	System	20 Aug 2020 20:52:19

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US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered '39.09753'	System	15 Dec 2020 22:28:20
User closed query 'BMI ≥ 40 kg/m2 yet participant is not recorded as at risk. Please review and provide, reconcile, or clarification.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 09:24:07
Query 'BMI ≥ 40 kg/m2 yet participant is not recorded as at risk. Please review and provide, reconcile, or clarification.' answered with 'Response updated' (Site from System).	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:38:08
User opened query 'BMI ≥ 40 kg/m2 yet participant is not recorded as at risk. Please review and provide, reconcile, or clarification.' (Site from System).	System	22 Sep 2020 13:58:00
User entered '43.03776'	System	22 Sep 2020 13:58:00
DataPoint set to visible.	System	20 Aug 2020 20:52:19

FDA-CBER-2022-1614-0110459

US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'kg/m2'	System	22 Sep 2020 13:58:00
DataPoint set to visible.	System	20 Aug 2020 20:52:19

FDA-CBER-2022-1614-0110460

US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 13:37:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	01 Oct 2020 13:37:03
User entered missing code ND - Not Done; reason for change Per Query Resolution	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:37:03
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 13:58:00
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:58:00

FDA-CBER-2022-1614-0110461

US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:58:00

FDA-CBER-2022-1614-0110462

US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:58:00

FDA-CBER-2022-1614-0110463

US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 13:37:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	01 Oct 2020 13:37:03
User entered missing code ND - Not Done; reason for change Per Query Resolution	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:37:03
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 13:58:00
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:58:00

FDA-CBER-2022-1614-0110464

US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'bpm'	System	01 Oct 2020 13:37:03
User entered empty.	System	22 Sep 2020 13:58:00

FDA-CBER-2022-1614-0110465

US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 13:37:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	01 Oct 2020 13:37:03
User entered missing code ND - Not Done; reason for change Per Query Resolution	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:37:03
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 13:58:00
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:58:00

FDA-CBER-2022-1614-0110466

US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'breaths/min'	System	01 Oct 2020 13:37:03
User entered empty.	System	22 Sep 2020 13:58:00

FDA-CBER-2022-1614-0110467

US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 13:37:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	01 Oct 2020 13:37:03
User entered missing code ND - Not Done; reason for change Per Query Resolution	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:37:03
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 13:58:00
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:58:00

FDA-CBER-2022-1614-0110468

US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'mmHg'	System	01 Oct 2020 13:37:03
User entered empty.	System	22 Sep 2020 13:58:00

FDA-CBER-2022-1614-0110469

US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 13:37:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	01 Oct 2020 13:37:03
User entered missing code ND - Not Done; reason for change Per Query Resolution	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:37:03
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 13:58:00
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 13:58:00

FDA-CBER-2022-1614-0110470

US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered 'mmHg'	System	01 Oct 2020 13:37:03
User entered empty.	System	22 Sep 2020 13:58:00

FDA-CBER-2022-1614-0110471

US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52

FDA-CBER-2022-1614-0110472

US3382085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:19:35
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52

FDA-CBER-2022-1614-0110473

US3382085
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 17:19:35
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:15:54

FDA-CBER-2022-1614-0110474

US3382085
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 17:19:35
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '20 Aug 2020'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:15:54

FDA-CBER-2022-1614-0110475

US3382085
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 17:19:35
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '20 Aug 2020'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:17:14

FDA-CBER-2022-1614-0110476

US3382085
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 17:19:35
Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:17:14

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US3382085
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 17:19:35
If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:17:14

FDA-CBER-2022-1614-0110478

US3382085
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 17:19:35
If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:17:14

FDA-CBER-2022-1614-0110479

US3382085
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 17:19:35
If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:17:14

US3382085
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 17:19:35
Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:17:14

US3382085
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 17:19:35
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:17:14

FDA-CBER-2022-1614-0110482

US3382085
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 17:19:35
Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:17:14

FDA-CBER-2022-1614-0110483

US3382085
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:20:41

FDA-CBER-2022-1614-0110484

US3382085
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '20 Aug 2020'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:20:41

FDA-CBER-2022-1614-0110485

US3382085
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Urine (URINE)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:20:41

FDA-CBER-2022-1614-0110486

US3382085
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Negative (NEGATIVE)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:20:41

FDA-CBER-2022-1614-0110487

US3382085
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:20:41

FDA-CBER-2022-1614-0110488

US3382085
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:20:41

FDA-CBER-2022-1614-0110489

US3382085
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:20:41

FDA-CBER-2022-1614-0110490

US3382085
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User entered empty.	System	22 Sep 2020 14:20:41

FDA-CBER-2022-1614-0110491

US3382085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:19:35
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

FDA-CBER-2022-1614-0110492

US3382085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:19:35
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

FDA-CBER-2022-1614-0110493

US3382085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:19:35

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

FDA-CBER-2022-1614-0110494

US3382085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:19:35
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

FDA-CBER-2022-1614-0110495

US3382085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:19:35
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

FDA-CBER-2022-1614-0110496

US3382085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:19:35
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

US3382085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:19:35
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

FDA-CBER-2022-1614-0110498

US3382085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:19:35
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

FDA-CBER-2022-1614-0110499

US3382085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:19:35
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

FDA-CBER-2022-1614-0110500

US3382085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:19:35
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

FDA-CBER-2022-1614-0110501

US3382085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:19:35
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

US3382085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:19:35
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

FDA-CBER-2022-1614-0110503

US3382085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:19:35
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'PROJECT MANAGER-CLINICAL RESEARCH'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

FDA-CBER-2022-1614-0110504

US3382085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:19:35
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

FDA-CBER-2022-1614-0110505

US3382085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:19:35
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

FDA-CBER-2022-1614-0110506

US3382085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:19:35

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

US3382085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:19:35
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

FDA-CBER-2022-1614-0110508

US3382085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:19:35

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

FDA-CBER-2022-1614-0110509

US3382085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:19:35
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '1'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

FDA-CBER-2022-1614-0110510

US3382085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:19:35
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

FDA-CBER-2022-1614-0110511

US3382085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:19:35
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:52
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:24:15

FDA-CBER-2022-1614-0110512

US3382085
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:19:35
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:52:03

FDA-CBER-2022-1614-0110513

US3382085
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:19:35
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 20:52:03

US3382085
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:19:35
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 19:10:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:52:03

FDA-CBER-2022-1614-0110515

US3382085
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:19:35
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User entered 'VISIT1'	System	20 Aug 2020 20:52:03

FDA-CBER-2022-1614-0110516

US3382085
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:19:35
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT(b) (4)	20 Aug 2020 18:34:17

FDA-CBER-2022-1614-0110517

US3382085
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:19:35
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:56:42
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:56:42
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 18:34:17
User entered '106414' (non-conformant).	RWS_ENDPOINT ENDPOINT(b) (4)	20 Aug 2020 18:34:17

FDA-CBER-2022-1614-0110518

US3382085
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:19:35
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
Comment added 'The subject was randomized as "not at risk" in error.'.	Jayasree Krishnankutty (b) (4)	20 Nov 2020 17:07:22
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 18:34:17

US3382085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:19:35

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)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 19:10:53
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Oct 2020 10:46:51
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'Responses added' (Site from DM).	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:37:44
User entered 'No (N)'	Sikhongi Phungwayo	22 Sep 2020 14:27:17
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Sep 2020 14:54:22

US3382085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:19:35

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)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:27:17

US3382085
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:19:35
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Severe obesity is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	15 Dec 2020 22:28:39
User entered 'No (N)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:28:39
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 22:17:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 22:17:23
User opened query 'Severe obesity is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	15 Dec 2020 22:17:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:17:23
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 22:17:08
User closed query 'Severe obesity is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	15 Dec 2020 22:17:08
User entered empty; reason for change Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:17:08
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 04:17:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 04:17:00
User opened query 'Severe obesity is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	23 Nov 2020 04:17:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	23 Nov 2020 04:17:00
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 04:16:39
User closed query 'Severe obesity is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	23 Nov 2020 04:16:39
User entered empty; reason for change Data Entry Error	Jayasree Krishnankutty (b) (4)	23 Nov 2020 04:16:39

FDA-CBER-2022-1614-0110522

US3382085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:19:35

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Comment added 'Subject randomized as "not at risk" in error.'.	Jayasree Krishnankutty (b) (4)	18 Nov 2020 17:58:51
User opened query 'Severe obesity is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	01 Oct 2020 13:37:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:37:37
User entered 'No (N)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:27:17

US3382085
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:19:35
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:27:17

FDA-CBER-2022-1614-0110524

US3382085
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:19:35
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:27:17

FDA-CBER-2022-1614-0110525

US3382085
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:19:35
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:27:17
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:37:11
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:47:43

FDA-CBER-2022-1614-0110526

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:19:35
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 11:35:12
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	Triny Cooper (b) (4)	06 Oct 2020 17:50:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Triny Cooper (b) (4)	06 Oct 2020 17:50:03
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 14:02:37
User entered '61' in	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110527

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:19:35
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Triny Cooper (b) (4)	06 Oct 2020 17:50:03
User entered '227.3' lb	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110528

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:19:35
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 11:35:12
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	Triny Cooper (b) (4)	06 Oct 2020 17:50:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Triny Cooper (b) (4)	06 Oct 2020 17:50:03
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 14:02:37
User entered '61' in	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110529

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:19:35
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Triny Cooper (b) (4)	06 Oct 2020 17:50:03
User entered '227.3' lb	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110530

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User accepted default value 'Pre-Dose (PREDOSE)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110531

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110532

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '20 Aug 2020'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110533

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '14:26'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110534

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User entered '20 Aug 2020 14:26'	System	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110535

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '98.1' F	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110536

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Oral (Oral)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110537

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110538

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '72'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110539

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User entered 'bpm'	System	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110540

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '14'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110541

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User entered 'breaths/min'	System	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110542

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '116'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110543

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User entered 'mmHg'	System	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110544

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '81'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User entered 'mmHg'	System	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110546

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:19:35
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 11:35:12
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	Triny Cooper (b) (4)	06 Oct 2020 17:50:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Triny Cooper (b) (4)	06 Oct 2020 17:50:03
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 14:02:37
User entered '61' in	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110547

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:19:35
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Triny Cooper (b) (4)	06 Oct 2020 17:50:03
User entered '227.3' lb	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110548

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User accepted default value 'Post-Dose (POSTDOSE)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110549

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110550

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '20 Aug 2020'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110551

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '15:36'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110552

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User entered '20 Aug 2020 15:36'	System	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110553

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '97.3' F	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110554

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Oral (Oral)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110555

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110556

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '73'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110557

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User entered 'bpm'	System	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110558

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '12'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110559

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User entered 'breaths/min'	System	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110560

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '124'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110561

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User entered 'mmHg'	System	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110562

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '89'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110563

US3382085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User entered 'mmHg'	System	22 Sep 2020 14:36:16

FDA-CBER-2022-1614-0110564

US3382085
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 17:19:35
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:25

US3382085
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 17:19:35
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:36:25

FDA-CBER-2022-1614-0110566

US3382085
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 06:27:09
Query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' answered with 'responses updated' (Site from DM).	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:38:59
User entered 'No (N)' reason for change: Per Query Resolution	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:38:54
User opened query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 10:11:21
User entered 'Yes (Y)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:39:04

FDA-CBER-2022-1614-0110567

US3382085
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty; reason for change Per Query Resolution	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:38:54
User entered '20 Aug 2020'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:39:04

FDA-CBER-2022-1614-0110568

US3382085
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty; reason for change Per Query Resolution	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:38:54
User entered 'Urine (URINE)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:39:04

FDA-CBER-2022-1614-0110569

US3382085
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty; reason for change Per Query Resolution	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:38:54
User entered 'Negative (NEGATIVE)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:39:04

FDA-CBER-2022-1614-0110570

US3382085
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty; reason for change Per Query Resolution	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:38:54
User entered 'No (N)'	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:39:04

FDA-CBER-2022-1614-0110571

US3382085
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:39:04

FDA-CBER-2022-1614-0110572

US3382085
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Sikhongi Phungwayo (b) (4)	22 Sep 2020 14:39:04

FDA-CBER-2022-1614-0110573

US3382085
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User entered empty.	System	22 Sep 2020 14:39:04

FDA-CBER-2022-1614-0110574

US3382085
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:19:35
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110575

US3382085
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:19:35
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110576

US3382085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:19:35

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)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:52:55

US3382085
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:19:35
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110578

US3382085
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:19:35
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110579

US3382085
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:19:35
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '15:00'	(b) (4), (b) (6)	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110580

US3382085
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:19:35
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User entered '20 Aug 2020 15:00'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110581

US3382085
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:19:35
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	20 Aug 2020 20:52:55

US3382085
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:19:35
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User entered 'ONCE'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110583

US3382085
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:19:35
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110584

US3382085
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:19:35
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:09:17

FDA-CBER-2022-1614-0110585

US3382085
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:19:35
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '20 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 18:09:17

FDA-CBER-2022-1614-0110586

US3382085
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:19:35
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '13:58'	(b) (4), (b) (6)	25 Aug 2020 18:09:17

FDA-CBER-2022-1614-0110587

US3382085
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:19:35
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User entered '20 Aug 2020 13:58'	System	25 Aug 2020 18:09:17

FDA-CBER-2022-1614-0110588

US3382085
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 17:19:35
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '20 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 18:11:37

FDA-CBER-2022-1614-0110589

US3382085
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:19:35
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		25 Aug 2020 18:11:37

FDA-CBER-2022-1614-0110590

US3382085
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:19:35
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:11:37

FDA-CBER-2022-1614-0110591

US3382085
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:19:35
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '13:57'	(b) (4), (b) (6)	25 Aug 2020 18:11:37

FDA-CBER-2022-1614-0110592

US3382085
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:19:35
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User entered '20 Aug 2020 13:57'	System	25 Aug 2020 18:11:37

FDA-CBER-2022-1614-0110593

US3382085
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:19:35
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		25 Aug 2020 18:11:37

FDA-CBER-2022-1614-0110594

US3382085
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:19:35
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:11:37

FDA-CBER-2022-1614-0110595

US3382085
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:19:35
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:11:37

FDA-CBER-2022-1614-0110596

US3382085
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:19:35
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User entered empty.	System	25 Aug 2020 18:11:37

FDA-CBER-2022-1614-0110597

US3382085
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 17:19:35
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:12:03

FDA-CBER-2022-1614-0110598

US3382085
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 17:19:35
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:59
User entered '1'	System	25 Aug 2020 18:12:03

FDA-CBER-2022-1614-0110599

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110600

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T15:53:46', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'fd24a3a9-eea2-47ae-8854-2d803bceb081'	System	20 Aug 2020 20:54:13
User entered 'Yes (Y)'	System	20 Aug 2020 20:54:13

FDA-CBER-2022-1614-0110601

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T15:53:58', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'fd24a3a9-eea2-47ae-8854-2d803bceb081'	System	20 Aug 2020 20:54:13
User entered '97.3'	System	20 Aug 2020 20:54:13

FDA-CBER-2022-1614-0110602

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T15:54:03', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'fd24a3a9-eea2-47ae-8854-2d803bceb081'	System	20 Aug 2020 20:54:13
User entered 'No (N)'	System	20 Aug 2020 20:54:13

FDA-CBER-2022-1614-0110603

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T15:54:09', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'fd24a3a9-eea2-47ae-8854-2d803bceb081'	System	20 Aug 2020 20:54:13
User entered '20 Aug 2020 15:54'	System	20 Aug 2020 20:54:13

FDA-CBER-2022-1614-0110604

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '20 Aug 2020 15:20'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110605

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '20 Aug 2020 17:50'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110606

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110607

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T20:10:57', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'a9b9651e-30a8-41cf-af3e-2ab983330a5e'	System	21 Aug 2020 01:11:26
User entered 'Yes (Y)'	System	21 Aug 2020 01:11:26

FDA-CBER-2022-1614-0110608

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T20:11:11', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'a9b9651e-30a8-41cf-af3e-2ab983330a5e'	System	21 Aug 2020 01:11:26
User entered '98.1'	System	21 Aug 2020 01:11:26

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T20:11:17', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'a9b9651e-30a8-41cf-af3e-2ab983330a5e'	System	21 Aug 2020 01:11:26
User entered 'No (N)'	System	21 Aug 2020 01:11:26

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T20:11:24', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'a9b9651e-30a8-41cf-af3e-2ab983330a5e'	System	21 Aug 2020 01:11:26
User entered '20 Aug 2020 20:11'	System	21 Aug 2020 01:11:26

FDA-CBER-2022-1614-0110611

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '20 Aug 2020 18:45'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110612

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110613

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 2'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110614

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:19:35
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T00:57:19', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '58777628-2849-4d18-b039-05f6d798f50b'	System	22 Aug 2020 05:57:37
User entered 'Yes (Y)'	System	22 Aug 2020 05:57:37

FDA-CBER-2022-1614-0110615

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:19:35
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T00:57:25', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '58777628-2849-4d18-b039-05f6d798f50b'	System	22 Aug 2020 05:57:37
User entered '98.7'	System	22 Aug 2020 05:57:37

FDA-CBER-2022-1614-0110616

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:19:35
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T00:57:28', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '58777628-2849-4d18-b039-05f6d798f50b'	System	22 Aug 2020 05:57:37
User entered 'No (N)'	System	22 Aug 2020 05:57:37

FDA-CBER-2022-1614-0110617

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:19:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T00:57:33', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '58777628-2849-4d18-b039-05f6d798f50b'	System	22 Aug 2020 05:57:37
User entered '22 Aug 2020 00:57'	System	22 Aug 2020 05:57:37

FDA-CBER-2022-1614-0110618

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110619

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110620

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 3'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110621

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:19:35
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T23:14:21', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '1bcfcb1d-ecdc-4b95-bf8f-bb2c8c52cd0d'	System	23 Aug 2020 04:14:34
User entered 'Yes (Y)'	System	23 Aug 2020 04:14:34

FDA-CBER-2022-1614-0110622

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:19:35
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T23:14:24', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '1bcfcb1d-ecdc-4b95-bf8f-bb2c8c52cd0d'	System	23 Aug 2020 04:14:34
User entered '97.9'	System	23 Aug 2020 04:14:34

FDA-CBER-2022-1614-0110623

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:19:35
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T23:14:27', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '1bcfcb1d-ecdc-4b95-bf8f-bb2c8c52cd0d'	System	23 Aug 2020 04:14:34
User entered 'No (N)'	System	23 Aug 2020 04:14:34

FDA-CBER-2022-1614-0110624

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:19:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T23:14:31', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '1bcfcb1d-ecdc-4b95-bf8f-bb2c8c52cd0d'	System	23 Aug 2020 04:14:34
User entered '22 Aug 2020 23:14'	System	23 Aug 2020 04:14:34

FDA-CBER-2022-1614-0110625

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110626

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110627

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 4'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110628

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:19:35
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-23T20:02:59', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'c9a09381-0b8c-4703-b139-48fffd95a431'	System	24 Aug 2020 01:03:54
User entered 'Yes (Y)'	System	24 Aug 2020 01:03:54

FDA-CBER-2022-1614-0110629

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:19:35
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-23T20:03:03', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'c9a09381-0b8c-4703-b139-48fffd95a431'	System	24 Aug 2020 01:03:54
User entered '98.5'	System	24 Aug 2020 01:03:54

FDA-CBER-2022-1614-0110630

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:19:35
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-23T20:03:08', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'c9a09381-0b8c-4703-b139-48fffd95a431'	System	24 Aug 2020 01:03:54
User entered 'No (N)'	System	24 Aug 2020 01:03:54

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:19:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-23T20:03:11', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'c9a09381-0b8c-4703-b139-48fffd95a431'	System	24 Aug 2020 01:03:54
User entered '23 Aug 2020 20:03'	System	24 Aug 2020 01:03:54

FDA-CBER-2022-1614-0110632

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110633

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110634

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 5'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110635

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:19:35
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-24T23:58:40', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '1de90c07-09b9-4c9a-8361-77e58085820a'	System	25 Aug 2020 04:59:29
User entered 'Yes (Y)'	System	25 Aug 2020 04:59:29

FDA-CBER-2022-1614-0110636

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:19:35
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-24T23:58:45', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '1de90c07-09b9-4c9a-8361-77e58085820a'	System	25 Aug 2020 04:59:29
User entered '98.8'	System	25 Aug 2020 04:59:29

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:19:35
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-24T23:58:47', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '1de90c07-09b9-4c9a-8361-77e58085820a'	System	25 Aug 2020 04:59:29
User entered 'No (N)'	System	25 Aug 2020 04:59:29

FDA-CBER-2022-1614-0110638

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:19:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-24T23:59:28', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '1de90c07-09b9-4c9a-8361-77e58085820a'	System	25 Aug 2020 04:59:29
User entered '24 Aug 2020 23:59'	System	25 Aug 2020 04:59:29

FDA-CBER-2022-1614-0110639

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110640

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110641

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 6'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110642

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:19:35
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-25T23:01:08', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'cbe6a855-d556-4247-9c39-e2cb553c2bdb'	System	26 Aug 2020 04:01:43
User entered 'Yes (Y)'	System	26 Aug 2020 04:01:43

FDA-CBER-2022-1614-0110643

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:19:35
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-25T23:01:31', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'cbe6a855-d556-4247-9c39-e2cb553c2bdb'	System	26 Aug 2020 04:01:43
User entered '98.0'	System	26 Aug 2020 04:01:43

FDA-CBER-2022-1614-0110644

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:19:35
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-25T23:01:34', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'cbe6a855-d556-4247-9c39-e2cb553c2bdb'	System	26 Aug 2020 04:01:43
User entered 'No (N)'	System	26 Aug 2020 04:01:43

FDA-CBER-2022-1614-0110645

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:19:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-25T23:01:41', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'cbe6a855-d556-4247-9c39-e2cb553c2bdb'	System	26 Aug 2020 04:01:43
User entered '25 Aug 2020 23:01'	System	26 Aug 2020 04:01:43

FDA-CBER-2022-1614-0110646

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110647

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110648

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 7'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110649

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:19:35
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-26T23:12:04', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '7ef7bc14-8f4e-41f3-86ce-a525b76bfd7d'	System	27 Aug 2020 04:12:52
User entered 'Yes (Y)'	System	27 Aug 2020 04:12:52

FDA-CBER-2022-1614-0110650

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:19:35
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-26T23:12:28', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '7ef7bc14-8f4e-41f3-86ce-a525b76bfd7d'	System	27 Aug 2020 04:12:52
User entered '98.5'	System	27 Aug 2020 04:12:52

FDA-CBER-2022-1614-0110651

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:19:35
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-26T23:12:45', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '7ef7bc14-8f4e-41f3-86ce-a525b76bfd7d'	System	27 Aug 2020 04:12:52
User entered 'No (N)'	System	27 Aug 2020 04:12:52

FDA-CBER-2022-1614-0110652

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:19:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-26T23:12:49', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '7ef7bc14-8f4e-41f3-86ce-a525b76bfd7d'	System	27 Aug 2020 04:12:52
User entered '26 Aug 2020 23:12'	System	27 Aug 2020 04:12:52

FDA-CBER-2022-1614-0110653

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110654

US3382085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110655

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110656

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00

FDA-CBER-2022-1614-0110657

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00

FDA-CBER-2022-1614-0110658

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00

FDA-CBER-2022-1614-0110659

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00

FDA-CBER-2022-1614-0110660

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00

FDA-CBER-2022-1614-0110661

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00

FDA-CBER-2022-1614-0110662

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00

FDA-CBER-2022-1614-0110663

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '20 Aug 2020 15:20'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110664

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '20 Aug 2020 17:50'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110665

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110666

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T20:11:43', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'fa8c6476-5dd4-4898-877e-6f056bcadfb6'	System	21 Aug 2020 01:49:24
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 01:49:24

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T20:11:48', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'fa8c6476-5dd4-4898-877e-6f056bcadfb6'	System	21 Aug 2020 01:49:24
User entered 'No (N)'	System	21 Aug 2020 01:49:24

FDA-CBER-2022-1614-0110668

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T20:48:16', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'fa8c6476-5dd4-4898-877e-6f056bcadfb6'	System	21 Aug 2020 01:49:24
User entered 'Yes (Y)'	System	21 Aug 2020 01:49:24

FDA-CBER-2022-1614-0110669

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T20:48:59', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'fa8c6476-5dd4-4898-877e-6f056bcadfb6'	System	21 Aug 2020 01:49:24
User entered '4'	System	21 Aug 2020 01:49:24

FDA-CBER-2022-1614-0110670

US3382085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:19:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T20:49:11', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'fa8c6476-5dd4-4898-877e-6f056bcadfb6'	System	21 Aug 2020 01:49:24
User entered 'None (1)'	System	21 Aug 2020 01:49:24

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T20:49:22', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'fa8c6476-5dd4-4898-877e-6f056bcadfb6'	System	21 Aug 2020 01:49:24
User entered '20 Aug 2020 20:49'	System	21 Aug 2020 01:49:24

FDA-CBER-2022-1614-0110672

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '20 Aug 2020 18:45'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110673

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110674

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 2'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110675

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:19:35
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T00:57:38', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '5a1f5e7f-c80f-4627-ad1a-2b1bad5e7726'	System	22 Aug 2020 05:58:16
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 05:58:16

FDA-CBER-2022-1614-0110676

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:19:35
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T00:57:59', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '5a1f5e7f-c80f-4627-ad1a-2b1bad5e7726'	System	22 Aug 2020 05:58:16
User entered 'No (N)'	System	22 Aug 2020 05:58:16

FDA-CBER-2022-1614-0110677

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:19:35
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T00:58:02', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '5a1f5e7f-c80f-4627-ad1a-2b1bad5e7726'	System	22 Aug 2020 05:58:16
User entered 'Yes (Y)'	System	22 Aug 2020 05:58:16

FDA-CBER-2022-1614-0110678

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:19:35
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T00:58:05', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '5a1f5e7f-c80f-4627-ad1a-2b1bad5e7726'	System	22 Aug 2020 05:58:16
User entered '2'	System	22 Aug 2020 05:58:16

US3382085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:19:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T00:58:11', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '5a1f5e7f-c80f-4627-ad1a-2b1bad5e7726'	System	22 Aug 2020 05:58:16
User entered 'None (1)'	System	22 Aug 2020 05:58:16

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:19:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T00:58:14', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '5a1f5e7f-c80f-4627-ad1a-2b1bad5e7726'	System	22 Aug 2020 05:58:16
User entered '22 Aug 2020 00:58'	System	22 Aug 2020 05:58:16

FDA-CBER-2022-1614-0110681

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110682

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110683

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 3'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110684

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:19:35
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T23:08:15', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '6c997917-2928-445f-8335-db94be8e73a5'	System	23 Aug 2020 04:08:30
User entered 'None (1)'	System	23 Aug 2020 04:08:30

FDA-CBER-2022-1614-0110685

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:19:35
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T23:08:17', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '6c997917-2928-445f-8335-db94be8e73a5'	System	23 Aug 2020 04:08:30
User entered 'No (N)'	System	23 Aug 2020 04:08:30

FDA-CBER-2022-1614-0110686

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:19:35
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T23:08:21', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '6c997917-2928-445f-8335-db94be8e73a5'	System	23 Aug 2020 04:08:30
User entered 'No (N)'	System	23 Aug 2020 04:08:30

FDA-CBER-2022-1614-0110687

US3382085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:19:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T23:08:24', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '6c997917-2928-445f-8335-db94be8e73a5'	System	23 Aug 2020 04:08:30
User entered 'None (1)'	System	23 Aug 2020 04:08:30

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:19:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T23:08:28', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '6c997917-2928-445f-8335-db94be8e73a5'	System	23 Aug 2020 04:08:30
User entered '22 Aug 2020 23:08'	System	23 Aug 2020 04:08:30

FDA-CBER-2022-1614-0110689

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110690

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110691

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 4'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110692

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:19:35
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-23T20:02:22', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '15e07256-9cfa-4392-87ab-7c85431d4fb1'	System	24 Aug 2020 01:03:46
User entered 'None (1)'	System	24 Aug 2020 01:03:46

FDA-CBER-2022-1614-0110693

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:19:35
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-23T20:02:25', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '15e07256-9cfa-4392-87ab-7c85431d4fb1'	System	24 Aug 2020 01:03:46
User entered 'No (N)'	System	24 Aug 2020 01:03:46

FDA-CBER-2022-1614-0110694

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:19:35
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-23T20:02:32', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '15e07256-9cfa-4392-87ab-7c85431d4fb1'	System	24 Aug 2020 01:03:46
User entered 'No (N)'	System	24 Aug 2020 01:03:46

FDA-CBER-2022-1614-0110695

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:19:35
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-23T20:02:46', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '15e07256-9cfa-4392-87ab-7c85431d4fb1'	System	24 Aug 2020 01:03:46
User entered 'None (1)'	System	24 Aug 2020 01:03:46

FDA-CBER-2022-1614-0110696

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:19:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-23T20:02:53', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '15e07256-9cfa-4392-87ab-7c85431d4fb1'	System	24 Aug 2020 01:03:46
User entered '23 Aug 2020 20:02'	System	24 Aug 2020 01:03:46

FDA-CBER-2022-1614-0110697

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110698

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110699

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 5'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110700

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:19:35
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-24T23:57:49', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '8ab42885-cd8f-4369-9e10-9f28eb2aff19'	System	25 Aug 2020 04:58:04
User entered 'None (1)'	System	25 Aug 2020 04:58:04

FDA-CBER-2022-1614-0110701

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:19:35
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-24T23:57:52', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '8ab42885-cd8f-4369-9e10-9f28eb2aff19'	System	25 Aug 2020 04:58:04
User entered 'No (N)'	System	25 Aug 2020 04:58:04

FDA-CBER-2022-1614-0110702

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:19:35
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-24T23:57:55', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '8ab42885-cd8f-4369-9e10-9f28eb2aff19'	System	25 Aug 2020 04:58:04
User entered 'No (N)'	System	25 Aug 2020 04:58:04

FDA-CBER-2022-1614-0110703

US3382085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:19:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-24T23:57:57', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '8ab42885-cd8f-4369-9e10-9f28eb2aff19'	System	25 Aug 2020 04:58:04
User entered 'None (1)'	System	25 Aug 2020 04:58:04

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:19:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-24T23:58:02', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '8ab42885-cd8f-4369-9e10-9f28eb2aff19'	System	25 Aug 2020 04:58:04
User entered '24 Aug 2020 23:58'	System	25 Aug 2020 04:58:04

FDA-CBER-2022-1614-0110705

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110706

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110707

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 6'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110708

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:19:35
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-25T23:00:30', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '25c136c0-4136-47cd-81d2-bba37acac87a'	System	26 Aug 2020 04:00:44
User entered 'None (1)'	System	26 Aug 2020 04:00:44

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:19:35
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-25T23:00:33', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '25c136c0-4136-47cd-81d2-bba37acac87a'	System	26 Aug 2020 04:00:44
User entered 'No (N)'	System	26 Aug 2020 04:00:44

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:19:35
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-25T23:00:35', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '25c136c0-4136-47cd-81d2-bba37acac87a'	System	26 Aug 2020 04:00:44
User entered 'No (N)'	System	26 Aug 2020 04:00:44

FDA-CBER-2022-1614-0110711

US3382085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:19:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-25T23:00:37', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '25c136c0-4136-47cd-81d2-bba37acac87a'	System	26 Aug 2020 04:00:44
User entered 'None (1)'	System	26 Aug 2020 04:00:44

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:19:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-25T23:00:41', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '25c136c0-4136-47cd-81d2-bba37acac87a'	System	26 Aug 2020 04:00:44
User entered '25 Aug 2020 23:00'	System	26 Aug 2020 04:00:44

FDA-CBER-2022-1614-0110713

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110714

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110715

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 7'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110716

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:19:35
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-26T23:11:16', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '59ccc4b9-564f-4a80-913f-9e7c24d9bd4d'	System	27 Aug 2020 04:11:29
User entered 'None (1)'	System	27 Aug 2020 04:11:29

FDA-CBER-2022-1614-0110717

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:19:35
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-26T23:11:19', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '59ccc4b9-564f-4a80-913f-9e7c24d9bd4d'	System	27 Aug 2020 04:11:29
User entered 'No (N)'	System	27 Aug 2020 04:11:29

FDA-CBER-2022-1614-0110718

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:19:35
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-26T23:11:21', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '59ccc4b9-564f-4a80-913f-9e7c24d9bd4d'	System	27 Aug 2020 04:11:29
User entered 'No (N)'	System	27 Aug 2020 04:11:29

FDA-CBER-2022-1614-0110719

US3382085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:19:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-26T23:11:23', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '59ccc4b9-564f-4a80-913f-9e7c24d9bd4d'	System	27 Aug 2020 04:11:29
User entered 'None (1)'	System	27 Aug 2020 04:11:29

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:19:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-26T23:11:27', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '59ccc4b9-564f-4a80-913f-9e7c24d9bd4d'	System	27 Aug 2020 04:11:29
User entered '26 Aug 2020 23:11'	System	27 Aug 2020 04:11:29

FDA-CBER-2022-1614-0110721

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110722

US3382085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110723

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110724

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00

FDA-CBER-2022-1614-0110725

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00

FDA-CBER-2022-1614-0110726

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00

FDA-CBER-2022-1614-0110727

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00

FDA-CBER-2022-1614-0110728

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00

FDA-CBER-2022-1614-0110729

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00

FDA-CBER-2022-1614-0110730

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00

FDA-CBER-2022-1614-0110731

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00

FDA-CBER-2022-1614-0110732

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '20 Aug 2020 15:20'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110733

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '20 Aug 2020 17:50'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110734

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110735

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T20:49:32', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '0419316a-688b-412b-b3a9-548fcf0c23ef'	System	21 Aug 2020 01:54:03
User entered 'None (0)'	System	21 Aug 2020 01:54:03

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T20:49:50', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '0419316a-688b-412b-b3a9-548fcf0c23ef'	System	21 Aug 2020 01:54:03
User entered 'None (0)'	System	21 Aug 2020 01:54:03

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T20:49:58', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '0419316a-688b-412b-b3a9-548fcf0c23ef'	System	21 Aug 2020 01:54:03
User entered 'None (0)'	System	21 Aug 2020 01:54:03

FDA-CBER-2022-1614-0110738

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T20:53:36', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '0419316a-688b-412b-b3a9-548fcf0c23ef'	System	21 Aug 2020 01:54:03
User entered 'None (0)'	System	21 Aug 2020 01:54:03

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T20:53:42', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '0419316a-688b-412b-b3a9-548fcf0c23ef'	System	21 Aug 2020 01:54:03
User entered 'None (0)'	System	21 Aug 2020 01:54:03

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T20:53:44', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '0419316a-688b-412b-b3a9-548fcf0c23ef'	System	21 Aug 2020 01:54:03
User entered 'None (0)'	System	21 Aug 2020 01:54:03

FDA-CBER-2022-1614-0110741

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T20:53:55', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '0419316a-688b-412b-b3a9-548fcf0c23ef'	System	21 Aug 2020 01:54:03
User entered 'No (N)'	System	21 Aug 2020 01:54:03

FDA-CBER-2022-1614-0110742

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-20T20:54:00', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '0419316a-688b-412b-b3a9-548fcf0c23ef'	System	21 Aug 2020 01:54:03
User entered '20 Aug 2020 20:54'	System	21 Aug 2020 01:54:03

FDA-CBER-2022-1614-0110743

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '20 Aug 2020 18:45'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110744

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110745

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 2'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110746

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:19:35
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T00:58:20', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '53bf248c-d426-4c4b-84d5-4ddbec3e37a4'	System	22 Aug 2020 05:59:04
User entered 'None (0)'	System	22 Aug 2020 05:59:04

FDA-CBER-2022-1614-0110747

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:19:35
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T00:58:27', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '53bf248c-d426-4c4b-84d5-4ddbec3e37a4'	System	22 Aug 2020 05:59:04
User entered 'No interference with activity (1)'	System	22 Aug 2020 05:59:04

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:19:35
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T00:58:30', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '53bf248c-d426-4c4b-84d5-4ddbec3e37a4'	System	22 Aug 2020 05:59:04
User entered 'None (0)'	System	22 Aug 2020 05:59:04

FDA-CBER-2022-1614-0110749

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:19:35
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T00:58:36', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '53bf248c-d426-4c4b-84d5-4ddbec3e37a4'	System	22 Aug 2020 05:59:04
User entered 'None (0)'	System	22 Aug 2020 05:59:04

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:19:35
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T00:58:39', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '53bf248c-d426-4c4b-84d5-4ddbec3e37a4'	System	22 Aug 2020 05:59:04
User entered 'None (0)'	System	22 Aug 2020 05:59:04

FDA-CBER-2022-1614-0110751

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:19:35
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T00:58:41', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '53bf248c-d426-4c4b-84d5-4ddbec3e37a4'	System	22 Aug 2020 05:59:04
User entered 'None (0)'	System	22 Aug 2020 05:59:04

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:19:35
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T00:58:45', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '53bf248c-d426-4c4b-84d5-4ddbec3e37a4'	System	22 Aug 2020 05:59:04
User entered 'No (N)'	System	22 Aug 2020 05:59:04

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:19:35
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T00:59:01', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '53bf248c-d426-4c4b-84d5-4ddbec3e37a4'	System	22 Aug 2020 05:59:04
User entered '22 Aug 2020 00:59'	System	22 Aug 2020 05:59:04

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110755

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110756

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 3'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110757

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:19:35
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T23:08:32', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'd88dc628-368f-4594-ba90-74764281e7db'	System	23 Aug 2020 04:09:03
User entered 'None (0)'	System	23 Aug 2020 04:09:03

FDA-CBER-2022-1614-0110758

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:19:35
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T23:08:36', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'd88dc628-368f-4594-ba90-74764281e7db'	System	23 Aug 2020 04:09:03
User entered 'None (0)'	System	23 Aug 2020 04:09:03

FDA-CBER-2022-1614-0110759

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:19:35
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T23:08:38', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'd88dc628-368f-4594-ba90-74764281e7db'	System	23 Aug 2020 04:09:03
User entered 'None (0)'	System	23 Aug 2020 04:09:03

FDA-CBER-2022-1614-0110760

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:19:35
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T23:08:40', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'd88dc628-368f-4594-ba90-74764281e7db'	System	23 Aug 2020 04:09:03
User entered 'None (0)'	System	23 Aug 2020 04:09:03

FDA-CBER-2022-1614-0110761

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:19:35
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T23:08:43', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'd88dc628-368f-4594-ba90-74764281e7db'	System	23 Aug 2020 04:09:03
User entered 'None (0)'	System	23 Aug 2020 04:09:03

FDA-CBER-2022-1614-0110762

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:19:35
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T23:08:45', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'd88dc628-368f-4594-ba90-74764281e7db'	System	23 Aug 2020 04:09:03
User entered 'None (0)'	System	23 Aug 2020 04:09:03

FDA-CBER-2022-1614-0110763

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:19:35
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T23:08:50', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'd88dc628-368f-4594-ba90-74764281e7db'	System	23 Aug 2020 04:09:03
User entered 'No (N)'	System	23 Aug 2020 04:09:03

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:19:35
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-22T23:08:57', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'd88dc628-368f-4594-ba90-74764281e7db'	System	23 Aug 2020 04:09:03
User entered '22 Aug 2020 23:08'	System	23 Aug 2020 04:09:03

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110766

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110767

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 4'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110768

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:19:35
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-23T20:03:17', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'ae6b20b0-4f76-4225-85b3-df2f4b8dfb94'	System	24 Aug 2020 01:04:13
User entered 'None (0)'	System	24 Aug 2020 01:04:13

FDA-CBER-2022-1614-0110769

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:19:35
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-23T20:03:20', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'ae6b20b0-4f76-4225-85b3-df2f4b8dfb94'	System	24 Aug 2020 01:04:13
User entered 'None (0)'	System	24 Aug 2020 01:04:13

FDA-CBER-2022-1614-0110770

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:19:35
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-23T20:03:23', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'ae6b20b0-4f76-4225-85b3-df2f4b8dfb94'	System	24 Aug 2020 01:04:13
User entered 'None (0)'	System	24 Aug 2020 01:04:13

FDA-CBER-2022-1614-0110771

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:19:35
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-23T20:03:25', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'ae6b20b0-4f76-4225-85b3-df2f4b8dfb94'	System	24 Aug 2020 01:04:13
User entered 'None (0)'	System	24 Aug 2020 01:04:13

FDA-CBER-2022-1614-0110772

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:19:35
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-23T20:03:27', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'ae6b20b0-4f76-4225-85b3-df2f4b8dfb94'	System	24 Aug 2020 01:04:13
User entered 'None (0)'	System	24 Aug 2020 01:04:13

FDA-CBER-2022-1614-0110773

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:19:35
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-23T20:03:29', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'ae6b20b0-4f76-4225-85b3-df2f4b8dfb94'	System	24 Aug 2020 01:04:13
User entered 'None (0)'	System	24 Aug 2020 01:04:13

FDA-CBER-2022-1614-0110774

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:19:35
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-23T20:03:40', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'ae6b20b0-4f76-4225-85b3-df2f4b8dfb94'	System	24 Aug 2020 01:04:13
User entered 'No (N)'	System	24 Aug 2020 01:04:13

FDA-CBER-2022-1614-0110775

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:19:35
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-23T20:03:46', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'ae6b20b0-4f76-4225-85b3-df2f4b8dfb94'	System	24 Aug 2020 01:04:13
User entered '23 Aug 2020 20:03'	System	24 Aug 2020 01:04:13

FDA-CBER-2022-1614-0110776

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110777

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110778

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 5'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110779

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:19:35
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-24T23:58:06', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'be9946a1-cfb2-43ab-a2e9-548d46680d02'	System	25 Aug 2020 04:58:34
User entered 'None (0)'	System	25 Aug 2020 04:58:34

FDA-CBER-2022-1614-0110780

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:19:35
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-24T23:58:09', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'be9946a1-cfb2-43ab-a2e9-548d46680d02'	System	25 Aug 2020 04:58:34
User entered 'None (0)'	System	25 Aug 2020 04:58:34

FDA-CBER-2022-1614-0110781

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:19:35
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-24T23:58:11', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'be9946a1-cfb2-43ab-a2e9-548d46680d02'	System	25 Aug 2020 04:58:34
User entered 'None (0)'	System	25 Aug 2020 04:58:34

FDA-CBER-2022-1614-0110782

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:19:35
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-24T23:58:13', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'be9946a1-cfb2-43ab-a2e9-548d46680d02'	System	25 Aug 2020 04:58:34
User entered 'None (0)'	System	25 Aug 2020 04:58:34

FDA-CBER-2022-1614-0110783

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:19:35
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-24T23:58:15', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'be9946a1-cfb2-43ab-a2e9-548d46680d02'	System	25 Aug 2020 04:58:34
User entered 'None (0)'	System	25 Aug 2020 04:58:34

FDA-CBER-2022-1614-0110784

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:19:35
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-24T23:58:17', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'be9946a1-cfb2-43ab-a2e9-548d46680d02'	System	25 Aug 2020 04:58:34
User entered 'None (0)'	System	25 Aug 2020 04:58:34

FDA-CBER-2022-1614-0110785

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:19:35
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-24T23:58:26', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'be9946a1-cfb2-43ab-a2e9-548d46680d02'	System	25 Aug 2020 04:58:34
User entered 'No (N)'	System	25 Aug 2020 04:58:34

FDA-CBER-2022-1614-0110786

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:19:35
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-24T23:58:30', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'be9946a1-cfb2-43ab-a2e9-548d46680d02'	System	25 Aug 2020 04:58:34
User entered '24 Aug 2020 23:58'	System	25 Aug 2020 04:58:34

FDA-CBER-2022-1614-0110787

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110788

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110789

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 6'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110790

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:19:35
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-25T23:00:45', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '6e002b0b-1e2f-4745-964a-5798eff2fcb5'	System	26 Aug 2020 04:01:06
User entered 'None (0)'	System	26 Aug 2020 04:01:06

FDA-CBER-2022-1614-0110791

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:19:35
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-25T23:00:47', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '6e002b0b-1e2f-4745-964a-5798eff2fcb5'	System	26 Aug 2020 04:01:06
User entered 'None (0)'	System	26 Aug 2020 04:01:06

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:19:35
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-25T23:00:50', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '6e002b0b-1e2f-4745-964a-5798eff2fcb5'	System	26 Aug 2020 04:01:06
User entered 'None (0)'	System	26 Aug 2020 04:01:06

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:19:35
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-25T23:00:52', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '6e002b0b-1e2f-4745-964a-5798eff2fcb5'	System	26 Aug 2020 04:01:06
User entered 'None (0)'	System	26 Aug 2020 04:01:06

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:19:35
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-25T23:00:54', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '6e002b0b-1e2f-4745-964a-5798eff2fcb5'	System	26 Aug 2020 04:01:06
User entered 'None (0)'	System	26 Aug 2020 04:01:06

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:19:35
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-25T23:00:56', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '6e002b0b-1e2f-4745-964a-5798eff2fcb5'	System	26 Aug 2020 04:01:06
User entered 'None (0)'	System	26 Aug 2020 04:01:06

FDA-CBER-2022-1614-0110796

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:19:35
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-25T23:00:59', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '6e002b0b-1e2f-4745-964a-5798eff2fcb5'	System	26 Aug 2020 04:01:06
User entered 'No (N)'	System	26 Aug 2020 04:01:06

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:19:35
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-25T23:01:03', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: '6e002b0b-1e2f-4745-964a-5798eff2fcb5'	System	26 Aug 2020 04:01:06
User entered '25 Aug 2020 23:01'	System	26 Aug 2020 04:01:06

FDA-CBER-2022-1614-0110798

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110799

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110800

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 7'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110801

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:19:35
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-26T23:11:31', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'c0132b9f-83a5-4a3c-b15b-87bb102996e2'	System	27 Aug 2020 04:11:59
User entered 'None (0)'	System	27 Aug 2020 04:11:59

FDA-CBER-2022-1614-0110802

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:19:35
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-26T23:11:34', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'c0132b9f-83a5-4a3c-b15b-87bb102996e2'	System	27 Aug 2020 04:11:59
User entered 'None (0)'	System	27 Aug 2020 04:11:59

FDA-CBER-2022-1614-0110803

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:19:35
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-26T23:11:36', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'c0132b9f-83a5-4a3c-b15b-87bb102996e2'	System	27 Aug 2020 04:11:59
User entered 'None (0)'	System	27 Aug 2020 04:11:59

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:19:35
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-26T23:11:38', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'c0132b9f-83a5-4a3c-b15b-87bb102996e2'	System	27 Aug 2020 04:11:59
User entered 'None (0)'	System	27 Aug 2020 04:11:59

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:19:35
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-26T23:11:40', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'c0132b9f-83a5-4a3c-b15b-87bb102996e2'	System	27 Aug 2020 04:11:59
User entered 'None (0)'	System	27 Aug 2020 04:11:59

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:19:35
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-26T23:11:43', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'c0132b9f-83a5-4a3c-b15b-87bb102996e2'	System	27 Aug 2020 04:11:59
User entered 'None (0)'	System	27 Aug 2020 04:11:59

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:19:35
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-26T23:11:45', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'c0132b9f-83a5-4a3c-b15b-87bb102996e2'	System	27 Aug 2020 04:11:59
User entered 'No (N)'	System	27 Aug 2020 04:11:59

FDA-CBER-2022-1614-0110808

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:19:35
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58040453-57FA-4D16-8118-ADC615AD54E1)', Time: '2020-08-26T23:11:57', User OID: 'PatientReportedOutcome (US3382085)', ODM File OID: 'c0132b9f-83a5-4a3c-b15b-87bb102996e2'	System	27 Aug 2020 04:11:59
User entered '26 Aug 2020 23:11'	System	27 Aug 2020 04:11:59

FDA-CBER-2022-1614-0110809

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:19:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110810

US3382085
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:19:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:32:00
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110811

US3382085
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:19:35
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:49
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:40:50

US3382085
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:19:35
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:49
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '27 Aug 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:40:50

US3382085
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:19:35
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:49
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Contact Made (CONTACT MADE)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:40:50

FDA-CBER-2022-1614-0110814

US3382085
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:19:35
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:49
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:40:50

FDA-CBER-2022-1614-0110815

US3382085
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:19:35
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:49
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:40:55

US3382085
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:19:35
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:49
User entered '1'	System	01 Oct 2020 13:40:55

FDA-CBER-2022-1614-0110817

US3382085
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:19:35
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:49
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:41:12

FDA-CBER-2022-1614-0110818

US3382085
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:19:35
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:49
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '03 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:41:12

FDA-CBER-2022-1614-0110819

US3382085
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:19:35
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:49
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Contact Made (CONTACT MADE)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:41:12

FDA-CBER-2022-1614-0110820

US3382085
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:19:35
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:49
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:41:12

FDA-CBER-2022-1614-0110821

US3382085
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:19:35
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:49
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:42:26

US3382085
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:19:35
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:35:49
User entered '1'	System	01 Oct 2020 13:42:26

FDA-CBER-2022-1614-0110823

US3382085
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:19:35
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:52:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:42:47

FDA-CBER-2022-1614-0110824

US3382085
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:19:35
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:52:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '10 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:42:47

FDA-CBER-2022-1614-0110825

US3382085
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:19:35
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:52:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Contact Made (CONTACT MADE)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:42:47

FDA-CBER-2022-1614-0110826

US3382085
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:19:35
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:52:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:42:47

US3382085
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:19:35
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:52:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:42:52

FDA-CBER-2022-1614-0110828

US3382085
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:19:35
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:52:16
User entered '1'	System	01 Oct 2020 13:42:52

FDA-CBER-2022-1614-0110829

US3382085
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:19:35
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:43:11

FDA-CBER-2022-1614-0110830

US3382085
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:19:35
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 08:01:27
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'SUBJECT'S VISIT WAS CONDUCTED OOW DUE TO RASH BASED ON PI DISCUSSION WITH MM' (Site from System).	Sinikka Green (b) (4) (b) (4)	18 Nov 2020 19:37:28
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	01 Oct 2020 13:43:11
User entered '25 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:43:11

FDA-CBER-2022-1614-0110831

US3382085
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:19:35
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Clinic (Clinic)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:43:11

FDA-CBER-2022-1614-0110832

US3382085
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:19:35
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User entered 'VISIT2'	System	01 Oct 2020 13:43:11

FDA-CBER-2022-1614-0110833

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User accepted default value 'Pre-Dose (PREDOSE)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110834

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110835

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '25 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110836

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '11:32'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110837

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User entered '25 Sep 2020 11:32'	System	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110838

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '98.4' F	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110839

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Oral (Oral)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110840

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110841

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '79'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110842

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User entered 'bpm'	System	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110843

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '14'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110844

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User entered 'breaths/min'	System	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110845

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '104'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110846

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User entered 'mmHg'	System	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110847

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '71'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110848

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:19:35
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User entered 'mmHg'	System	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110849

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User accepted default value 'Post-Dose (POSTDOSE)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110850

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	01 Oct 2020 13:45:25
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	01 Oct 2020 13:45:10
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110851

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty; reason for change Data Entry Error	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:25
User entered '25 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110853

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User entered empty.	System	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110854

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110855

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110856

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110857

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110858

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User entered empty.	System	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110859

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110860

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User entered empty.	System	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110861

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110862

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User entered empty.	System	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110863

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110864

US3382085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:19:35
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User entered empty.	System	01 Oct 2020 13:45:10

FDA-CBER-2022-1614-0110865

US3382085
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:19:35
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:37

FDA-CBER-2022-1614-0110866

US3382085
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:19:35
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:37

FDA-CBER-2022-1614-0110867

US3382085
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Per CDM: Childbearing potential noted as “Yes” yet pregnancy test not completed. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 07:36:30
Query 'Per CDM: Childbearing potential noted as “Yes” yet pregnancy test not completed. Kindly review and update else clarify.' answered with 'vaccine was delayed' (Site from DM).	Sinikka Green (b) (4) (b) (4)	02 Dec 2020 18:51:14
User entered 'No (N)' reason for change: Data Entry Error	Sinikka Green (b) (4) (b) (4)	02 Dec 2020 18:51:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Sinikka Green (b) (4) (b) (4)	02 Dec 2020 18:49:28
User opened query 'Per CDM: Childbearing potential noted as “Yes” yet pregnancy test not completed. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:45:37
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:58

US3382085
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Dec 2020 18:51:04
Query 'Date of Test is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	02 Dec 2020 18:51:04
User entered empty; reason for change Data Entry Error	Sinikka Green (b) (4) (b) (4)	02 Dec 2020 18:51:04
User opened query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Dec 2020 18:49:28
User entered '20 Aug 2020' reason for change: Data Entry Error	Sinikka Green (b) (4) (b) (4)	02 Dec 2020 18:49:28
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:58

US3382085
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty; reason for change Data Entry Error	Sinikka Green (b) (4) (b) (4)	02 Dec 2020 18:51:04
User entered 'Urine (URINE)' reason for change: Data Entry Error	Sinikka Green (b) (4) (b) (4)	02 Dec 2020 18:49:28
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:58

US3382085
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty; reason for change Data Entry Error	Sinikka Green (b) (4) (b) (4)	02 Dec 2020 18:51:04
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	Sinikka Green (b) (4) (b) (4)	02 Dec 2020 18:49:28
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:58

FDA-CBER-2022-1614-0110871

US3382085
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)' reason for change: Data Entry Error	Sinikka Green (b) (4) (b) (4)	02 Dec 2020 18:49:28
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:58

FDA-CBER-2022-1614-0110872

US3382085
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:58

FDA-CBER-2022-1614-0110873

US3382085
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:45:58

FDA-CBER-2022-1614-0110874

US3382085
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:19:35
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User entered empty.	System	01 Oct 2020 13:45:58

FDA-CBER-2022-1614-0110875

US3382085
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:19:35
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:49:10

FDA-CBER-2022-1614-0110876

US3382085
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:19:35
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:49:10

FDA-CBER-2022-1614-0110877

US3382085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:19:35

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)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'PI wants to wait until rash has resolved until administering medication; visit has been rescheduled'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:49:10

US3382085
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:19:35
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User entered empty.	System	01 Oct 2020 13:49:10

FDA-CBER-2022-1614-0110879

US3382085
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:19:35
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:49:10

FDA-CBER-2022-1614-0110880

US3382085
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:19:35
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:49:10

FDA-CBER-2022-1614-0110881

US3382085
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:19:35
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User entered empty.	System	01 Oct 2020 13:49:10

FDA-CBER-2022-1614-0110882

US3382085
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:19:35
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:49:10

FDA-CBER-2022-1614-0110883

US3382085
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:19:35
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User entered empty.	System	01 Oct 2020 13:49:10

FDA-CBER-2022-1614-0110884

US3382085
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:19:35
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User entered empty.	System	01 Oct 2020 13:49:10

FDA-CBER-2022-1614-0110885

US3382085
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:19:35
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:49:17

FDA-CBER-2022-1614-0110886

US3382085
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:19:35
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:49:17

FDA-CBER-2022-1614-0110887

US3382085
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:19:35
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:49:17

FDA-CBER-2022-1614-0110888

US3382085
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:19:35
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User entered empty.	System	01 Oct 2020 13:49:17

FDA-CBER-2022-1614-0110889

US3382085
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 17:19:35
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:49:24

FDA-CBER-2022-1614-0110890

US3382085
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:19:35
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:49:24

FDA-CBER-2022-1614-0110891

US3382085
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:19:35
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:49:24

FDA-CBER-2022-1614-0110892

US3382085
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:19:35
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:49:24

FDA-CBER-2022-1614-0110893

US3382085
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:19:35
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User entered empty.	System	01 Oct 2020 13:49:24

FDA-CBER-2022-1614-0110894

US3382085
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:19:35
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:49:24

FDA-CBER-2022-1614-0110895

US3382085
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:19:35
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:49:24

FDA-CBER-2022-1614-0110896

US3382085
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:19:35
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:49:24

FDA-CBER-2022-1614-0110897

US3382085
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:19:35
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User entered empty.	System	01 Oct 2020 13:49:24

FDA-CBER-2022-1614-0110898

US3382085
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:19:35
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:50:28

FDA-CBER-2022-1614-0110899

US3382085
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:19:35
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:36
User entered '1'	System	01 Oct 2020 13:50:28

FDA-CBER-2022-1614-0110900

US3382085
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:19:35
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	30 Mar 2021 13:48:46
User entered 'No (N)'	Colleen Jacobsen (b) (4)	28 Mar 2021 03:09:24

FDA-CBER-2022-1614-0110901

US3382085
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:19:35
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	30 Mar 2021 13:48:46
User entered empty.	Colleen Jacobsen (b) (4)	28 Mar 2021 03:09:24

FDA-CBER-2022-1614-0110902

US3382085
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:19:35
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	30 Mar 2021 13:48:46
User entered empty.	Colleen Jacobsen (b) (4)	28 Mar 2021 03:09:24

FDA-CBER-2022-1614-0110903

US3382085
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:19:35
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	30 Mar 2021 13:48:46
User entered empty.	Colleen Jacobsen (b) (4)	28 Mar 2021 03:09:24

US3382085
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:19:35
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	30 Mar 2021 13:48:46
User entered 'No (N)'	Colleen Jacobsen (b) (4)	28 Mar 2021 03:09:28

FDA-CBER-2022-1614-0110905

US3382085
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:19:35
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User entered empty.	System	28 Mar 2021 03:09:28

FDA-CBER-2022-1614-0110906

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 64'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110907

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

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)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

Have you been exposed to someone with 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)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

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)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110912

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110913

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110914

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110915

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110916

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110917

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110918

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110919

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110920

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110921

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110922

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110923

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110924

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110925

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110926

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110927

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110928

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

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)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110932

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06
Data entry locked.	System	20 Aug 2020 20:52:55
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110933

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06
Data entry locked.	System	20 Aug 2020 20:52:55
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110934

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 71'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110935

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

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)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

Have you been exposed to someone with 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)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

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)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110940

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110941

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110942

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110943

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110944

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110945

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110946

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110947

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110948

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110949

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110950

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110951

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110952

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110953

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110954

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110955

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110956

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

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)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110960

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06
Data entry locked.	System	20 Aug 2020 20:52:55
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 20:52:55

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06
Data entry locked.	System	20 Aug 2020 20:52:55
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110962

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 78'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110963

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

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)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

Have you been exposed to someone with 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)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

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)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110968

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110969

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110970

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110971

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110973

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110974

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110975

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110976

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110977

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110978

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110979

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110981

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110982

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110983

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110984

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

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)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110988

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06
Data entry locked.	System	20 Aug 2020 20:52:55
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110989

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06
Data entry locked.	System	20 Aug 2020 20:52:55
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 20:52:55

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06
Data entry locked.	System	20 Aug 2020 20:52:55
User entered 'Day 92'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0110991

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

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)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

Have you been exposed to someone with 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)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

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)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110996

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110997

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110998

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0110999

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0111000

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0111001

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0111002

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0111003

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0111004

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0111005

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0111006

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0111007

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0111008

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0111009

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0111010

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0111011

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0111012

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

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)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:19:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06

FDA-CBER-2022-1614-0111016

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06
Data entry locked.	System	20 Aug 2020 20:52:55
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 20:52:55

FDA-CBER-2022-1614-0111017

US3382085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:19:35
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:58:06
Data entry locked.	System	20 Aug 2020 20:52:55
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 20:52:55

US3382085
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 17:19:35
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:50:39

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

FDA-CBER-2022-1614-0111020

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Generalized, Right deltoid, etc), TYPE (e.g., Macular, Papular, etc) of RASH and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 12:28:51
Query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Generalized, Right deltoid, etc), TYPE (e.g., Macular, Papular, etc) of RASH and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'at this time the information is unk. pt ultimately w/d consent ' (Site from DM).	Sinikka Green (b) (4) (b) (4)	15 Dec 2020 18:35:34
User opened query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Generalized, Right deltoid, etc), TYPE (e.g., Macular, Papular, etc) of RASH and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 00:16:28
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis allergic, LLT: Allergic rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:59:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:59:52
Data point term sent to Coder	System	01 Oct 2020 13:51:56
User entered 'allergic rash - unknown etiology'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111021

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111022

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111023

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '12 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111025

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	01 Oct 2020 13:52:01
User entered empty; reason for change Per Query Resolution	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:52:01
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	01 Oct 2020 13:51:48
User entered '19:00'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111026

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User entered empty.	System	01 Oct 2020 13:52:01
User entered '12 Sep 2020 19:00'	System	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111027

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Per CDM CLR re-query: Thank you for your answer. Please confirm if this AE was still ongoing at the time of withdrew consent or end date is available. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 13:35:46
Query 'Per CDM CLR re-query: Thank you for your answer. Please confirm if this AE was still ongoing at the time of withdrew consent or end date is available. Thank you!' answered with 'Yes this AE was still ongoing at the time of withdrew consent.' (Site from DM).	Jayasree Krishnankutty (b) (4)	22 Dec 2020 00:59:19
User opened query 'Per CDM CLR re-query: Thank you for your answer. Please confirm if this AE was still ongoing at the time of withdrew consent or end date is available. Thank you!' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 12:30:33
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).		16 Dec 2020 12:30:33
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'subject withdrew consent' (Site from DM).	Sinikka Green (b) (4) (b) (4)	15 Dec 2020 18:35:46
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 10:52:28
User entered 'Yes (Y)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111029

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User entered empty.	System	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111031

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111033

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111034

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111035

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111036

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111037

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111038

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Not Related (NOT RELATED)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111044

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Not Related (NOT RELATED)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111045

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'None (NONE)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111046

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '1'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111049

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111050

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111051

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:51:48

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User entered '0'	System	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111053

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User entered '1'	System	01 Oct 2020 13:51:48

FDA-CBER-2022-1614-0111054

US3382085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:19:35
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

FDA-CBER-2022-1614-0111055

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 09 Jun 2021 17:19:35
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:52:13

FDA-CBER-2022-1614-0111056

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:19:35
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;LEVONORGESTREL, PRODUCTSYNONYM: LESSINA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 01:02:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 01:02:40
Data point term sent to Coder	System	22 Dec 2020 01:02:13
Coding entries removed.	Jayasree Krishnankutty (b) (4)	22 Dec 2020 01:01:36
User entered 'LESSINA' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	22 Dec 2020 01:01:36
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;LEVONORGESTREL, PRODUCTSYNONYM: LESSINA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 00:44:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 00:44:47
Data point term sent to Coder	System	15 Dec 2020 21:47:38
Coding entries removed.	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:46:39
Coding entries removed.	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:46:39
User entered 'LESSINA (0.1 mg/20 mcg)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:46:39

US3382085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:19:35

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;LEVONORGESTREL, PRODUCTSYNONYM: LESSINA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 08:15:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 08:15:39
Data point term sent to Coder	System	01 Oct 2020 13:52:57
User entered 'lessina birth control'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:52:45

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:19:35
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 08:46:39
Query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' answered with 'Corrected' (Site from DM).	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:46:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:46:39
User opened query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 10:41:46
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:52:45

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:19:35
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'contraception' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:46:39
User entered 'birth control'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:52:45

FDA-CBER-2022-1614-0111060

US3382085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:19:35

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Per CDM CLR re-query: Thank you for your answer. However, please remove dosages and units from "Name of medication" field and add under "Dose per administration" and "Dose unit". Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 13:34:47
Query 'Per CDM CLR re-query: Thank you for your answer. However, please remove dosages and units from "Name of medication" field and add under "Dose per administration" and "Dose unit". Thank you!' answered with 'dose and dose unit changed. dosages and units from name of medication removed' (Site from DM).	Jayasree Krishnankutty (b) (4)	22 Dec 2020 01:02:26
User entered '0.1/20' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	22 Dec 2020 01:01:36
User opened query 'Per CDM CLR re-query: Thank you for your answer. However, please remove dosages and units from "Name of medication" field and add under "Dose per administration" and "Dose unit". Thank you!' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 08:47:43
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).		16 Dec 2020 08:47:43
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' answered with 'dose included with the name' (Site from DM).	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:47:22
User entered '1' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:46:39
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 10:42:00

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:19:35
Dose per administration

Audit	User	Time (GMT)
User entered '35'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:52:45

FDA-CBER-2022-1614-0111062

US3382085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:19:35

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Other (OTHER)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	22 Dec 2020 01:01:36
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:46:39
User entered 'mg (mg)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:52:45

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:19:35
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'mg/MCG' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	22 Dec 2020 01:01:36
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:52:45

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:19:35
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'once daily (QD)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:52:45

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:19:35
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:52:45

FDA-CBER-2022-1614-0111066

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:19:35
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Oral (ORAL)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:52:45

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:19:35
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:52:45

FDA-CBER-2022-1614-0111068

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:19:35
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'un UNK 1999'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:52:45

FDA-CBER-2022-1614-0111069

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:52:45

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:19:35
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:52:45

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:19:35
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:52:45

FDA-CBER-2022-1614-0111072

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:19:35
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:52:45

FDA-CBER-2022-1614-0111073

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:19:35
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User entered '1'	System	01 Oct 2020 13:52:45

FDA-CBER-2022-1614-0111074

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User entered '1'	System	01 Oct 2020 13:52:45

FDA-CBER-2022-1614-0111075

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User entered '804 (804)'	System	01 Oct 2020 13:52:45

FDA-CBER-2022-1614-0111076

US3382085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:19:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:55:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:55:20
Data point term sent to Coder	System	01 Oct 2020 13:53:58
User entered 'lexapro'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:19

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:19:35
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:19

FDA-CBER-2022-1614-0111078

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:19:35
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'depression'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:19

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:19:35
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '20'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:19

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:19:35
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'mg (mg)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:19

FDA-CBER-2022-1614-0111081

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:19:35
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:19

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:19:35
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'once daily (QD)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:19

FDA-CBER-2022-1614-0111083

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:19:35
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:19

FDA-CBER-2022-1614-0111084

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:19:35
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Oral (ORAL)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:19

FDA-CBER-2022-1614-0111085

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:19:35
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:19

FDA-CBER-2022-1614-0111086

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:19:35
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'un UNK 2014'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:19

FDA-CBER-2022-1614-0111087

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:19

FDA-CBER-2022-1614-0111088

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:19:35
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:19

FDA-CBER-2022-1614-0111089

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:19:35
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:19

FDA-CBER-2022-1614-0111090

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:19:35
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:19

FDA-CBER-2022-1614-0111091

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:19:35
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User entered '1'	System	01 Oct 2020 13:53:19

FDA-CBER-2022-1614-0111092

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User entered '1'	System	01 Oct 2020 13:53:19

FDA-CBER-2022-1614-0111093

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User entered '804 (804)'	System	01 Oct 2020 13:53:19

FDA-CBER-2022-1614-0111094

US3382085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:19:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: LAMOTRIGINE, PRODUCTSYNONYM: LAMICTAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:55:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:55:19
Data point term sent to Coder	System	01 Oct 2020 13:53:58
User entered 'lamictal'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:47

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:19:35
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:47

FDA-CBER-2022-1614-0111096

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:19:35
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'depression'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:47

FDA-CBER-2022-1614-0111097

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:19:35
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '300'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:47

FDA-CBER-2022-1614-0111098

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:19:35
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'mg (mg)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:47

FDA-CBER-2022-1614-0111099

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:19:35
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:47

FDA-CBER-2022-1614-0111100

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:19:35
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'once daily (QD)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:47

FDA-CBER-2022-1614-0111101

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:19:35
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:47

FDA-CBER-2022-1614-0111102

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:19:35
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Oral (ORAL)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:47

FDA-CBER-2022-1614-0111103

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:19:35
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:47

FDA-CBER-2022-1614-0111104

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:19:35
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'un UNK 2014'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:47

FDA-CBER-2022-1614-0111105

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:47

FDA-CBER-2022-1614-0111106

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:19:35
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Yes (Y)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:47

FDA-CBER-2022-1614-0111107

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:19:35
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:47

FDA-CBER-2022-1614-0111108

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:19:35
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:53:47

FDA-CBER-2022-1614-0111109

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:19:35
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User entered '1'	System	01 Oct 2020 13:53:47

FDA-CBER-2022-1614-0111110

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User entered '1'	System	01 Oct 2020 13:53:47

FDA-CBER-2022-1614-0111111

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User entered '804 (804)'	System	01 Oct 2020 13:53:47

FDA-CBER-2022-1614-0111112

US3382085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:19:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:22
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:56:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:56:13
Data point term sent to Coder	System	01 Oct 2020 13:54:59
User entered 'zyrtec'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:54:18

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:19:35
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:22
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:54:18

FDA-CBER-2022-1614-0111114

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:19:35
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:22
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'seasonal allergies'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:54:18

FDA-CBER-2022-1614-0111115

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:19:35
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:22
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '10'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:54:18

FDA-CBER-2022-1614-0111116

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:19:35
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:22
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'mg (mg)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:54:18

FDA-CBER-2022-1614-0111117

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:19:35
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:22
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:54:18

FDA-CBER-2022-1614-0111118

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:19:35
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:22
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'once daily (QD)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:54:18

FDA-CBER-2022-1614-0111119

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:19:35
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:22
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:54:18

FDA-CBER-2022-1614-0111120

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:19:35
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:22
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Oral (ORAL)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:54:18

FDA-CBER-2022-1614-0111121

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:19:35
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:22
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:54:18

FDA-CBER-2022-1614-0111122

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:19:35
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:22
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'un UNK 2000'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:54:18

FDA-CBER-2022-1614-0111123

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:22
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:54:18

FDA-CBER-2022-1614-0111124

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:19:35
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:22
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:54:18

FDA-CBER-2022-1614-0111125

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:19:35
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:22
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '08 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:54:18

FDA-CBER-2022-1614-0111126

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:19:35
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:22
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:54:18

FDA-CBER-2022-1614-0111127

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:19:35
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:22
User entered '1'	System	01 Oct 2020 13:54:18

FDA-CBER-2022-1614-0111128

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:22
User entered '1'	System	01 Oct 2020 13:54:18

FDA-CBER-2022-1614-0111129

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:22
User entered '804 (804)'	System	01 Oct 2020 13:54:18

FDA-CBER-2022-1614-0111130

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:19:35
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:57
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:32:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:32:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: ACRIVASTINE, PRODUCTSYNONYM: BENADRYL [ACRIVASTINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:01:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:01:48
Data point term sent to Coder	System	01 Oct 2020 13:55:01
User entered 'benadryl'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:00

FDA-CBER-2022-1614-0111131

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:19:35
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:57
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:00

FDA-CBER-2022-1614-0111132

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:19:35
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:57
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'allergic rash - unknown etiology'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:00

FDA-CBER-2022-1614-0111133

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:19:35
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:57
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '25'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:00

FDA-CBER-2022-1614-0111134

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:19:35
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:57
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'mg (mg)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:00

FDA-CBER-2022-1614-0111135

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:19:35
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:57
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:00

FDA-CBER-2022-1614-0111136

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:19:35
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:57
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'once daily (QD)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:00

FDA-CBER-2022-1614-0111137

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:19:35
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:57
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:00

FDA-CBER-2022-1614-0111138

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:19:35
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:57
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Oral (ORAL)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:00

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:19:35
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:57
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:00

FDA-CBER-2022-1614-0111140

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:19:35
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:57
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '13 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:00

FDA-CBER-2022-1614-0111141

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:57
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:00

FDA-CBER-2022-1614-0111142

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:19:35
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:57
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:00

FDA-CBER-2022-1614-0111143

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:19:35
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:57
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '14 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:00

FDA-CBER-2022-1614-0111144

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:19:35
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:57
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:00

FDA-CBER-2022-1614-0111145

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:19:35
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:57
User entered '1'	System	01 Oct 2020 13:55:00

FDA-CBER-2022-1614-0111146

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:57
User entered '1'	System	01 Oct 2020 13:55:00

FDA-CBER-2022-1614-0111147

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:57
User entered '804 (804)'	System	01 Oct 2020 13:55:00

FDA-CBER-2022-1614-0111148

US3382085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:19:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:00
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:57:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:57:06
Data point term sent to Coder	System	01 Oct 2020 13:56:02
User entered 'singulair'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:30

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:19:35
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:00
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:30

FDA-CBER-2022-1614-0111150

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:19:35
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:00
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'allergic rash - unknown etiology'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:30

FDA-CBER-2022-1614-0111151

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:19:35
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:00
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '10'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:30

FDA-CBER-2022-1614-0111152

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:19:35
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:00
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'mg (mg)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:30

FDA-CBER-2022-1614-0111153

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:19:35
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:00
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:30

FDA-CBER-2022-1614-0111154

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:19:35
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:00
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'once daily (QD)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:30

FDA-CBER-2022-1614-0111155

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:19:35
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:00
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:30

FDA-CBER-2022-1614-0111156

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:19:35
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:00
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Oral (ORAL)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:30

FDA-CBER-2022-1614-0111157

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:19:35
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:00
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:30

FDA-CBER-2022-1614-0111158

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:19:35
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:00
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '15 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:30

FDA-CBER-2022-1614-0111159

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:00
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:30

FDA-CBER-2022-1614-0111160

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:19:35
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:00
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:30

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:19:35
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:00
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '22 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:30

FDA-CBER-2022-1614-0111162

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:19:35
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:00
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:55:30

FDA-CBER-2022-1614-0111163

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:19:35
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:00
User entered '1'	System	01 Oct 2020 13:55:30

FDA-CBER-2022-1614-0111164

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:00
User entered '1'	System	01 Oct 2020 13:55:30

FDA-CBER-2022-1614-0111165

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:00
User entered '804 (804)'	System	01 Oct 2020 13:55:30

FDA-CBER-2022-1614-0111166

US3382085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:19:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:05
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:48:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:48:54
Data point term sent to Coder	System	01 Oct 2020 13:57:03
User entered 'methylprednisolone'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:00

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:19:35
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:05
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:00

FDA-CBER-2022-1614-0111168

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:19:35
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:05
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'allergic reaction - unknown etiology'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:00

FDA-CBER-2022-1614-0111169

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:19:35
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:05
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '24'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:00

FDA-CBER-2022-1614-0111170

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:19:35
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:05
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'mg (mg)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:00

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:19:35
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:05
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:00

FDA-CBER-2022-1614-0111172

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:19:35
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:05
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'once (ONCE)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:48:17
User entered 'other (OTHER)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:00

US3382085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:19:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:05
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Per DM CLR: Please review review to record actual frequency of administration of this medication (e.g. Once, Once Daily, BID, etc.). Update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 08:48:17
Query 'Per DM CLR: Please review review to record actual frequency of administration of this medication (e.g. Once, Once Daily, BID, etc.). Update as appropriate, otherwise clarify. ' answered with 'corrected' (Site from DM).	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:48:30
User entered empty; reason for change Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:48:17
User opened query 'Per DM CLR: Please review review to record actual frequency of administration of this medication (e.g. Once, Once Daily, BID, etc.). Update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 10:45:07
User entered 'oto'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:00

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:19:35
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:05
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Oral (ORAL)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:00

FDA-CBER-2022-1614-0111175

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:19:35
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:05
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:00

FDA-CBER-2022-1614-0111176

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:19:35
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:05
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '15 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:00

FDA-CBER-2022-1614-0111177

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:05
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:00

FDA-CBER-2022-1614-0111178

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:19:35
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:05
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:00

FDA-CBER-2022-1614-0111179

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:19:35
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:05
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '15 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:00

FDA-CBER-2022-1614-0111180

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:19:35
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:05
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:00

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:19:35
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:05
User entered empty.	System	01 Oct 2020 13:57:00

FDA-CBER-2022-1614-0111182

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:05
User entered empty.	System	01 Oct 2020 13:57:00

FDA-CBER-2022-1614-0111183

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:05
User entered empty.	System	01 Oct 2020 13:57:00

FDA-CBER-2022-1614-0111184

US3382085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:19:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:10
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:48:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:48:54
Data point term sent to Coder	System	01 Oct 2020 13:58:05
User entered 'methylprednisolone'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:35

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:19:35
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:10
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:35

FDA-CBER-2022-1614-0111186

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:19:35
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:10
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'allergic reaction - unknown etiology'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:35

FDA-CBER-2022-1614-0111187

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:19:35
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:10
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '20'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:35

FDA-CBER-2022-1614-0111188

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:19:35
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:10
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'mg (mg)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:35

FDA-CBER-2022-1614-0111189

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:19:35
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:10
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:35

FDA-CBER-2022-1614-0111190

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:19:35
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:10
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'once (ONCE)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:49:48
User entered 'other (OTHER)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:35

US3382085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:19:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:10
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Per DM CLR: Please review review to record actual frequency of administration of this medication (e.g. Once, Once Daily, BID, etc.). Update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 08:48:26
Query 'Per DM CLR: Please review review to record actual frequency of administration of this medication (e.g. Once, Once Daily, BID, etc.). Update as appropriate, otherwise clarify. ' answered with 'corrected' (Site from DM).	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:49:56
User entered empty; reason for change Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:49:48
User opened query 'Per DM CLR: Please review review to record actual frequency of administration of this medication (e.g. Once, Once Daily, BID, etc.). Update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 10:45:36
User entered 'oto'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:35

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:19:35
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:10
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Oral (ORAL)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:35

FDA-CBER-2022-1614-0111193

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:19:35
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:10
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:35

FDA-CBER-2022-1614-0111194

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:19:35
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:10
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '16 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:35

FDA-CBER-2022-1614-0111195

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:10
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:35

FDA-CBER-2022-1614-0111196

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:19:35
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:10
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:35

FDA-CBER-2022-1614-0111197

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:19:35
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:10
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '16 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:35

FDA-CBER-2022-1614-0111198

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:19:35
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:10
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:57:35

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:19:35
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:10
User entered empty.	System	01 Oct 2020 13:57:35

FDA-CBER-2022-1614-0111200

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:10
User entered empty.	System	01 Oct 2020 13:57:35

FDA-CBER-2022-1614-0111201

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:10
User entered empty.	System	01 Oct 2020 13:57:35

FDA-CBER-2022-1614-0111202

US3382085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:19:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Impor(b) (4) (b) (4)	02 Oct 2020 12:48:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:48:54
Data point term sent to Coder	System	01 Oct 2020 13:59:08
User entered 'methylprednisolone'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:12

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:19:35
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:12

FDA-CBER-2022-1614-0111204

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:19:35
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'allergic reaction - unknown etiology'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:12

FDA-CBER-2022-1614-0111205

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:19:35
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '16' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:51:06
User entered '12'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:12

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:19:35
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'mg (mg)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:12

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:19:35
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:12

FDA-CBER-2022-1614-0111208

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:19:35
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'once (ONCE)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:51:06
User entered 'other (OTHER)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:12

US3382085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:19:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Per DM CLR: Please review review to record actual frequency of administration of this medication (e.g. Once, Once Daily, BID, etc.). Update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 08:48:32
Query 'Per DM CLR: Please review review to record actual frequency of administration of this medication (e.g. Once, Once Daily, BID, etc.). Update as appropriate, otherwise clarify. ' answered with 'corrected' (Site from DM).	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:51:13
User entered empty; reason for change Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:51:06
User opened query 'Per DM CLR: Please review review to record actual frequency of administration of this medication (e.g. Once, Once Daily, BID, etc.). Update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 10:47:06
User entered 'oto'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:12

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:19:35
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Oral (ORAL)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:12

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:19:35
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:12

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:19:35
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '17 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:12

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:12

FDA-CBER-2022-1614-0111214

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:19:35
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:12

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:19:35
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '17 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:12

FDA-CBER-2022-1614-0111216

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:19:35
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:12

FDA-CBER-2022-1614-0111217

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:19:35
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User entered empty.	System	01 Oct 2020 13:58:12

FDA-CBER-2022-1614-0111218

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User entered empty.	System	01 Oct 2020 13:58:12

FDA-CBER-2022-1614-0111219

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User entered empty.	System	01 Oct 2020 13:58:12

FDA-CBER-2022-1614-0111220

US3382085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:19:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:20
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Impor(b) (4) (b) (4)	02 Oct 2020 12:48:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Impor(b) (4) (b) (4)	02 Oct 2020 12:48:54
Data point term sent to Coder	System	01 Oct 2020 13:59:09
User entered 'methylprednisolone'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:43

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:19:35
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:20
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:43

FDA-CBER-2022-1614-0111222

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:19:35
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:20
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'allergic reaction - unknown etiology'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:43

FDA-CBER-2022-1614-0111223

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:19:35
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:20
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '12' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:51:44
User entered '8'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:43

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:19:35
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:20
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'mg (mg)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:43

FDA-CBER-2022-1614-0111225

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:19:35
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:20
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:43

FDA-CBER-2022-1614-0111226

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:19:35
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:20
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'once (ONCE)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:51:44
User entered 'other (OTHER)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:43

US3382085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:19:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:20
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Per DM CLR: Please review review to record actual frequency of administration of this medication (e.g. Once, Once Daily, BID, etc.). Update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 08:48:39
Query 'Per DM CLR: Please review review to record actual frequency of administration of this medication (e.g. Once, Once Daily, BID, etc.). Update as appropriate, otherwise clarify. ' answered with 'corrected' (Site from DM).	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:51:59
User entered empty; reason for change Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 21:51:44
User opened query 'Per DM CLR: Please review review to record actual frequency of administration of this medication (e.g. Once, Once Daily, BID, etc.). Update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 10:47:47
User entered 'oto'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:43

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:19:35
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:20
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Oral (ORAL)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:43

FDA-CBER-2022-1614-0111229

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:19:35
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:20
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:43

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:19:35
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:20
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '18 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:43

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:20
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:43

FDA-CBER-2022-1614-0111232

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:19:35
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:20
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:43

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:19:35
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:20
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '18 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:43

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:19:35
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:20
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:58:43

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:19:35
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:20
User entered empty.	System	01 Oct 2020 13:58:43

FDA-CBER-2022-1614-0111236

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:20
User entered empty.	System	01 Oct 2020 13:58:43

FDA-CBER-2022-1614-0111237

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:20
User entered empty.	System	01 Oct 2020 13:58:43

FDA-CBER-2022-1614-0111238

US3382085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:19:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:26
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:48:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:48:55
Data point term sent to Coder	System	01 Oct 2020 14:00:12
User entered 'methylprednisolone'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:21

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:19:35
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:26
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:21

FDA-CBER-2022-1614-0111240

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:19:35
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:26
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'allergic reaction - unknown etiology'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:21

FDA-CBER-2022-1614-0111241

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:19:35
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:26
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '8' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:03:52
User entered '4'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:21

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:19:35
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:26
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'mg (mg)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:21

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:19:35
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:26
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:21

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:19:35
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:26
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'once (ONCE)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:03:52
User entered 'other (OTHER)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:21

US3382085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:19:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:26
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query 'Per DM CLR: Please review review to record actual frequency of administration of this medication (e.g. Once, Once Daily, BID, etc.). Update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 08:48:44
Query 'Per DM CLR: Please review review to record actual frequency of administration of this medication (e.g. Once, Once Daily, BID, etc.). Update as appropriate, otherwise clarify. ' answered with 'corrected' (Site from DM).	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:04:00
User entered empty; reason for change Data Entry Error	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:03:52
User opened query 'Per DM CLR: Please review review to record actual frequency of administration of this medication (e.g. Once, Once Daily, BID, etc.). Update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 10:48:25
User entered 'oto'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:21

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:19:35
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:26
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Oral (ORAL)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:21

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:19:35
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:26
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:21

FDA-CBER-2022-1614-0111248

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:19:35
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:26
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '19 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:21

FDA-CBER-2022-1614-0111249

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:26
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:21

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:19:35
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:26
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:21

FDA-CBER-2022-1614-0111251

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:19:35
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:26
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '19 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:21

FDA-CBER-2022-1614-0111252

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:19:35
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:26
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:21

FDA-CBER-2022-1614-0111253

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:19:35
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:26
User entered empty.	System	01 Oct 2020 13:59:21

FDA-CBER-2022-1614-0111254

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:26
User entered empty.	System	01 Oct 2020 13:59:21

FDA-CBER-2022-1614-0111255

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:26
User entered empty.	System	01 Oct 2020 13:59:21

FDA-CBER-2022-1614-0111256

US3382085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:19:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:29
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:18:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:18:15
Data point term sent to Coder	System	06 Oct 2020 17:54:00
User closed query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	System	06 Oct 2020 17:53:20
Query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' answered with 'updated' (Site from System).	Triny Cooper (b) (4)	06 Oct 2020 17:53:20
Data point term sent to Coder	System	06 Oct 2020 17:52:57
User entered 'ZYRTEC-(Cetirizine)' reason for change: Data Entry Error	Triny Cooper (b) (4)	06 Oct 2020 17:52:55
User opened query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	Coder Import (b) (4) (b) (4)	02 Oct 2020 08:33:36
Data point term sent to Coder	System	01 Oct 2020 14:00:12
User entered 'zyrtec'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:54

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:19:35
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:29
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:54

FDA-CBER-2022-1614-0111258

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:19:35
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:29
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'allergic reaction - unknown etiology'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:54

FDA-CBER-2022-1614-0111259

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:19:35
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:29
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '20'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:54

FDA-CBER-2022-1614-0111260

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:19:35
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:29
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'mg (mg)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:54

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:19:35
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:29
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:54

FDA-CBER-2022-1614-0111262

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:19:35
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:29
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'once daily (QD)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:54

FDA-CBER-2022-1614-0111263

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:19:35
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:29
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:54

FDA-CBER-2022-1614-0111264

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:19:35
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:29
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Oral (ORAL)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:54

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:19:35
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:29
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:54

FDA-CBER-2022-1614-0111266

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:19:35
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:29
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '15 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:54

FDA-CBER-2022-1614-0111267

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:29
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:54

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:19:35
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:29
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:54

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:19:35
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:29
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '20 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:54

FDA-CBER-2022-1614-0111270

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:19:35
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:29
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 13:59:54

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:19:35
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:29
User entered '1'	System	01 Oct 2020 13:59:54

FDA-CBER-2022-1614-0111272

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:29
User entered '1'	System	01 Oct 2020 13:59:54

FDA-CBER-2022-1614-0111273

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:29
User entered '804 (804)'	System	01 Oct 2020 13:59:54

FDA-CBER-2022-1614-0111274

US3382085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:19:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:34
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 02:18:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 02:18:49
Data point term sent to Coder	System	15 Dec 2020 22:05:59
User entered 'Methylprednisolone'	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:05:43

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:19:35
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:34
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:05:43

FDA-CBER-2022-1614-0111276

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:19:35
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:34
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Allergic dermatitis of unknown etiology'	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:05:43

FDA-CBER-2022-1614-0111277

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:19:35
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:34
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '4'	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:05:43

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:19:35
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:34
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'mg (mg)'	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:05:43

FDA-CBER-2022-1614-0111279

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:19:35
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:34
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:05:43

FDA-CBER-2022-1614-0111280

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:19:35
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:34
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'once (ONCE)'	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:05:43

FDA-CBER-2022-1614-0111281

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:19:35
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:34
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:05:43

FDA-CBER-2022-1614-0111282

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:19:35
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:34
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'Oral (ORAL)'	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:05:43

FDA-CBER-2022-1614-0111283

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:19:35
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:34
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered empty.	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:05:43

FDA-CBER-2022-1614-0111284

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:19:35
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:34
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '20 Sep 2020'	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:05:43

FDA-CBER-2022-1614-0111285

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:34
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '0'	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:05:43

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:19:35
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:34
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:05:43

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:19:35
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:34
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '20 Sep 2020'	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:05:43

FDA-CBER-2022-1614-0111288

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:19:35
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:34
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Jayasree Krishnankutty (b) (4)	15 Dec 2020 22:05:43

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:19:35
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:34
User entered empty.	System	15 Dec 2020 22:05:43

FDA-CBER-2022-1614-0111290

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:34
User entered empty.	System	15 Dec 2020 22:05:43

FDA-CBER-2022-1614-0111291

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:34
User entered empty.	System	15 Dec 2020 22:05:43

FDA-CBER-2022-1614-0111292

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:19:35
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

FDA-CBER-2022-1614-0111293

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:19:35
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

FDA-CBER-2022-1614-0111294

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:19:35
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

FDA-CBER-2022-1614-0111295

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:19:35
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

FDA-CBER-2022-1614-0111296

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:19:35
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

FDA-CBER-2022-1614-0111297

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:19:35
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

FDA-CBER-2022-1614-0111298

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:19:35
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

FDA-CBER-2022-1614-0111299

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:19:35
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

FDA-CBER-2022-1614-0111300

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:19:35
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

FDA-CBER-2022-1614-0111301

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:19:35
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

FDA-CBER-2022-1614-0111302

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:19:35
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

FDA-CBER-2022-1614-0111303

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:19:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

FDA-CBER-2022-1614-0111304

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:19:35
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

FDA-CBER-2022-1614-0111305

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:19:35
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

FDA-CBER-2022-1614-0111306

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:19:35
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:19:35
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

FDA-CBER-2022-1614-0111308

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

FDA-CBER-2022-1614-0111309

US3382085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 17:19:35
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44

FDA-CBER-2022-1614-0111310

US3382085
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 09 Jun 2021 17:19:35
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'No (N)'	Michelle Jackson (b) (4) (b) (4)	01 Oct 2020 14:00:00

FDA-CBER-2022-1614-0111311

US3382085
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 09 Jun 2021 17:19:35
Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:32:31
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered '25 Sep 2020'	Sikhongi Phungwayo (b) (4)	10 Dec 2020 14:37:13

FDA-CBER-2022-1614-0111312

US3382085
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 09 Jun 2021 17:19:35
Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:32:31
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User entered 'AE (specify) (ADVERSE EVENT)'	Sikhongi Phungwayo (b) (4)	10 Dec 2020 14:37:13

FDA-CBER-2022-1614-0111313

US3382085

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:19:35

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:32:31
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 19:10:53
User closed query "Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' .' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 07:38:27
Query "Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' .' answered with 'changed to AE#1.' (Site from DM).	Jayasree Krishnankutty (b) (4)	27 Dec 2020 05:09:36
User entered 'AE #1' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	27 Dec 2020 05:09:21
User opened query "Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' .' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 06:53:23
User entered 'Allergic Rash-Unknown etiology'	Sikhongi Phungwayo (b) (4)	10 Dec 2020 14:37:13

US3382085
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:19:35
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:32:31
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	30 Mar 2021 19:59:21
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	30 Mar 2021 17:57:13
User entered '25 Sep 2020' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	30 Mar 2021 17:57:13
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	30 Mar 2021 17:56:59
User entered '25 Sep 2021'	Colleen Jacobsen (b) (4)	30 Mar 2021 17:56:59

US3382085
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:19:35
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:32:31
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	30 Mar 2021 19:59:21
User entered 'AE (specify) (ADVERSE EVENT)'	Colleen Jacobsen (b) (4)	30 Mar 2021 17:56:59

FDA-CBER-2022-1614-0111316

US3382085

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:19:35

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	28 Apr 2021 03:22:02
Data hard locked.	(b) (4), (b) (6)	7 Apr 2021 13:32:31
User closed query 'Per CDM: As per CCGs, enter "#1" in the Other, Specify field.' (Site from DM).		9 Apr 2021 13:16:38
Query 'Per CDM: As per CCGs, enter "#1" in the Other, Specify field.' answered with 'Changed AE #1' (Site from DM).	Jayasree Krishnankutty (b) (4)	18 Apr 2021 13:32:17
Signature has been broken.	Jayasree Krishnankutty (b) (4)	18 Apr 2021 13:32:05
User entered 'AE #1' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	18 Apr 2021 13:32:05
User opened query 'Per CDM: As per CCGs, enter "#1" in the Other, Specify field.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 15:21:46
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	30 Mar 2021 19:59:21
User entered 'Allergic Rash- Unknown etiology'	Colleen Jacobsen (b) (4)	30 Mar 2021 17:56:59

US3382085
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:19:35
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:32:31
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	30 Mar 2021 19:59:21
User entered empty.	Colleen Jacobsen (b) (4)	30 Mar 2021 17:56:59

FDA-CBER-2022-1614-0111318

US3382085
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:19:35
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:32:31
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	30 Mar 2021 19:59:21
User entered empty.	Colleen Jacobsen (b) (4)	30 Mar 2021 17:56:59

FDA-CBER-2022-1614-0111319

US3382085
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:19:35
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:32:31
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	30 Mar 2021 19:59:21
User entered empty.	Colleen Jacobsen (b) (4)	30 Mar 2021 17:56:59

FDA-CBER-2022-1614-0111320

US3382085
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:19:35
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:32:31
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	30 Mar 2021 19:59:21
User entered empty.	Colleen Jacobsen (b) (4)	30 Mar 2021 17:56:59

FDA-CBER-2022-1614-0111321